A STUDY TO DETERMINE THE EFFICACY OF A Ø,2 µm AIR VENTING FINAL IN-LINE INTRAVENOUS FILTER IN REDUCING THE COMPLICATIONS OF INTRAVENOUS THERAPY

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APPENDICES

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Abstract

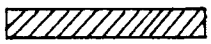
The effect of a Ø,2 µm air venting in-line filter on the incidence of post-infusion phlebitis was studied in a prospective, controlled, observer-blind investigation of 132 infusions. The filters were changed daily and the infusions were allowed to continue until no longer required, or until there was a reason for discontinuation. Microbiological evaluation of filters, skin at the site of cannulation immediately prior to removal of cannulae, and cannula tips was performed. Particle size analyses of the commonly used intravenous infusion fluids and medicines was also carried out.

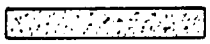
The incidence of phlebitis was significantly reduced by the inclusion of the filter in-line. The efficacy of the filter in reducing phlebitis was most pronounced when intravenous antimicrobial agents, especially the cephalosporins, were administered.

Micro-organisms were isolated from 13% (28/2Ø9) of filters which originated from 31% (16/32) of infusions with filters in-line. A relationship could not be established between the number of filters used per infusion or the number of intravenous additives to the infusion system. Phlebitis was not associated with microbial contamination of cannula tips.

Medicines for intravenous administration, especially the powders to be reconstituted prior to administration, were heavily contaminated with particulate matter prior to filtration.

Abbreviations and codes

 Duration of in-line filter period

 Duration of control period; no end-line filter

Key to alcohol intake

1 Total abstainer

2 Moderate or social drinker ie one who drinks on social occasions, or with meals, but rarely to excess

3 Sporadic excessive drinker ie one who drinks excessively on festive occasions

4 Heavy social drinker ie one who habitually drinks heavily, primarily on social occasions, and suffers frequent episodes of intoxication

5 Alcoholic ie one who has developed a disease called alcoholism

6 Indeterminate

Based on page 8 of Alcoholism. The total treatment approach (113)

Key to smoking

1 Total abstainer

2 Ø - 9 cigarettes daily

3 1Ø-19 cigarettes daily

4 2Ø-39 cigarettes daily

5 over 4Ø cigarettes daily

6 Indeterminate

Based on page 29 of Smoking and Health (114)

bd	twice daily
d	day
°C	degree Celsius
cm	centimetre
D5	dextrose 5% solution in water
D5 in NS	dextrose 5% solution in normal saline
2'-DCF	2'-Deoxycoformycin
ESR	erythrocyte sedimentation rate
g	gram
g.dl	gram per decilitre
h	hour
IM	intramuscular injection
iu	international unit
IV	intravenous
.l	per litre
M	Maintelyte®
.m	per minute
mg	milligram
mm.h	millimetre per hour
mm Hg	millimetre of mercury
mu	million units
m/v	mass in volume
No.	number
N/A	not applicable
Neb	oral spray solution
NG	no growth
NS	normal saline
PB	Plasmolyte B®
po	by mouth
prn	when necessary

qid	four times a day
RF	Rehydration fluid
sp	species
subling	sublingual
tds	three times a day
u	unit
µg	microgram
µm	micrometre
WBC	white blood cell count

Active ingredients of proprietary products

Codis®	=	Acetylsalicylic acid	500mg
		Codeine phosphate	8mg
		Calcium carbonate	150mg
		Anhydrous citric acid	50mg
Kloref®	=	Betaine hydrochloride	1,035g
		Potassium bicarbonate	0,675g
Moduretic®	=	Amiloride hydrochloride	5mg
		Hydrochlorothiazide	50mg
Panadeine®	=	Paracetamol	500mg
		Codeine phosphate	8 mg

Solphyllin® = Etofylline 10mg+ Theophylline 80mg/ 15 ml

Infusion fluids

Maintelyte®	= Dextrose 10%		
	Na^+ 35	millimoles/litre	
	K^+ 25	"	"
	Mg^{++} 2,5	"	"
	Cl^- 65	"	"
Plasmolyte B®	= Na^+ 130	millimoles/litre	
	K^+ 4	"	"
	Mg^{++} 1,5	"	"
	Cl^- 109	"	"
	HCO_3^- 28	"	"

Rehydration fluid = Dextrose 5% in 0,45% sodium chloride solution

CHAPTER 1

INTRODUCTION and LITERATURE REVIEW

1.1 Introduction

The cholera epidemic of 1832 in Scotland heralded the clinical use of crystalloid solutions for intravenous infusion therapy (1). Dr T Latta, in order to rehydrate the cholera victims, "...resolved to throw the fluid immediately into the circulation." No adverse effects were recorded, but Dr Latta warned "...the vein should be treated with much delicacy to avoid phlebitis."

Since then many problems associated with intravenous infusion therapy have been recognised, the most frequent being phlebitis, which is reported to occur in Ø,9-1ØØ% of patients receiving intravenous infusions. This wide variation in the reported incidence of phlebitis depends to some degree on the criteria used for assessment, and the duration of cannulation. Catheter sepsis, pyrogenic reactions and septicaemia may also develop and complicate the recovery of patients on intravenous infusion therapy.

Infusion phlebitis is primarily a physicochemical phenomenon, produced by phlebitogenic substances administered intravenously, and mechanical irritation by the cannula. However, it can also be produced by microbial (2) and particulate contamination (3,4) of the intravenous fluid, and by infection of the cannula tip or cannula wound (5,6).

If microbial and particulate contamination of intravenous fluids does lead to phlebitis and other complications, then it would be reasonable to propose that final in-line filters may reduce the incidence of complications due to intravenous infusion therapy.

1.2 Literature review

1.2.1 Incidence of phlebitis

The overall incidence of phlebitis reported in the literature varies from Ø.9 to 1ØØ%. Bogen (6) reported an incidence of phlebitis of Ø,9%, when the cannula was in place for less than 12 hours, 2,9% when in place for 12 to 36 hours, and 37% when the cannula remained in place for 36 to 72 hours; phlebitis was recorded when inflammation was noted along the course of the infused vein. Frazer et al. (7) reported an incidence of phlebitis of 57% within 2,47 days, as judged by erythema and tenderness; the incidence of phlebitis increased from 4,3% after 24 hours of infusion to 1ØØ% after 5 days. Smallman et al. (8) found an incidence of phlebitis of 100% within 3,4 days, as judged by the presence of tenderness, erythema, oedema or warmth.

Gough and Woodruff (9) reported a statistically significant variation ($p < 0,01$) in phlebitis between two surveys, undertaken by them in the same wards, but separated by an interval of 1 month. In the first survey, 42% of patients (61/147) developed phlebitis and in the second 22% (21/94).

The authors gave no criteria for the assessment of phlebitis, and were unable to explain this variation. The surveys also showed that the incidence of phlebitis increased with the duration of cannulation. In the second survey the mean time the cannulae remained in situ, without phlebitis developing, was 1,64 days as compared to 2,55 days for patients developing phlebitis. Cannulae left in situ for 48 hours or less carried a lower risk of phlebitis than those left in situ for over 48 hours ($p < 0,01$).

Other studies also show that the risk of phlebitis developing increases with duration of infusion.

Sexton and Gravney (10) found that 12/136 (9%) cannulations resulted in phlebitis. Only 2,5% of patients, with a duration of cannulation of 24 hours or less, developed phlebitis whereas 50% developed phlebitis, when the duration of cannulation was over 72 hours. The mean duration of cannulation was 25,3 hours, for patients not developing phlebitis, and 86,2 hours for those developing phlebitis. Phlebitis was recorded if two or more of the following signs were present at the cannulation site: erythema, tenderness, warmth, oedema, induration and purulence.

Brown (11) reported an incidence of 8% phlebitis on the first day of his study and 18% on the second day, with an overall incidence of 27% (43/158 infusions); 69% of cases of phlebitis appeared within 48 hours.

Bartz (12) reported an overall incidence of phlebitis of

36,7% (11/30 infusions) and that 6/7 patients, with a duration of infusion over 36 hours, developed phlebitis. The mean duration of infusion for patients, who did not develop phlebitis, was 21,36 ± 13,78 hours whereas for those developing phlebitis it was 36,97 ± 28,69 hours.

In a study of 11 patients, over 65 years of age with septic phlebitis, the cannulae had been in situ over 48 hours, and the duration of cannulation ranged from 2 to 11 days (13).

Hessov (14) in 1981 concluded, from a survey of 7 other published papers, that the incidence of phlebitis was 12-34% after 24 hours and 36-65% after 48 hours. One of these 7 papers (15) reported a phlebitis rate of 70% when the duration of cannulation exceeded 72 hours, and that thrombophlebitis was significantly more common in infusions of 36-72 hours duration than in infusions of less than 36 hours duration (an incidence of 52% and 18%, respectively).

1.2.2 Clinical studies on in-line filters

Clinical studies published to date have evaluated filters included in peripheral lines primarily for their ability to reduce the incidence of phlebitis. Four papers (3,16,17,18) have also investigated their efficacy in preventing changes in parameters such as temperature, respiratory rate, pulse rate, blood pressure, erythrocyte sedimentation rate, white blood cell count and reduction in duration of hospitalization.

The first published study on the clinical use of in-line filters, by Wilmore and Dudrick in 1969 (19), was uncontrolled and gave no criteria for the assessment of phlebitis or other complications of intravenous therapy. The authors state " No systemic signs of bacteremia, septicemia, or local signs of phlebitis were observed..." following the use of 0,45 µm filters left in-line for 72 hours. This study was important because it demonstrated that final in-line filters would remove microbial contaminants from infusion systems.

Ryan et al. (16), in a non-blind study of 100 postoperative patients at the Kentucky Medical Center, found that a 0,45 µm filter in-line for 72 hours reduced the incidence of phlebitis from 45% in the nonfilter group to 2%. Phlebitis was recorded if erythema, induration and a palpable venous cord were present. Temperature, respiratory rate, pulse rate and diastolic pressure were reported to be more normal in the filter group.

Three further papers from the above centre, one being a composite of the other two, also demonstrate a significant reduction in the incidence of phlebitis between the control and filter groups, in double-blind studies (3,20,21). In the study by DeLuca et al. (3), the incidence of phlebitis was reduced from 62% to 25% (over 72 hours) and, in the study by Maddox et al. (20), from 35% to 10% (over 48 hours) by an in-line filter.

DeLuca et al. (3) used a 0,45 µ m filter; phlebitis was

recorded as present if two of the following criteria were observed : pain, tenderness, erythema, swelling or a palpable venous cord. The incidence of phlebitis was almost three times greater when the filter and set were changed 24 hourly (32%), than when left unchanged for the 72 hours of the study (12%). Changes in temperature, respiratory rate, pulse rate, blood pressure, white blood cell count and erythrocyte sedimentation rate were monitored to determine if a systemic response to infusion phlebitis could be determined by these means. No significant differences in terms of vital signs were noted between the study groups, however, a significant rise in white cell count and an increase in sedimentation rate were observed in patients receiving unfiltered fluids.

Maddox et al. (20) investigated the effects of a 0,22 µm filter, as well as heparin and hydrocortisone, on the incidence of phlebitis in patients receiving cephalothin for 48 hours. Sixty percent (12/20) of patients developed grade 1+ phlebitis (pain at the intravenous site) in the control group and 20% (4/20) in the filter group; 35% (7/20) developed grade 2+ phlebitis (pain with erythema and/or swelling) in the control group compared to 10% (2/20) in the filter group.

Rusho and Bair (18) demonstrated, in their double-blind study, that the phlebitis rate of a control group (27%) was significantly greater ($p < 0,05$) than that of a 0,45 µm filter group (6%), but not significantly different from that of a 5 µm filter group (22%). They also found that, for the

5 µm and Ø,45 µm filter groups, the duration of hospitalization was reduced by 3,4 and 3,3 days, respectively, from the control group's 13,6 days. All patients received cephalothin 2g 6 hourly and dextrose 5% in 0,2% sodium chloride solution for 56 to 60 hours; filters were changed daily. Phlebitis was identified by pain, erythema and a hard and tender indurated vein.

In contrast to Rusho and Bair (18), Evans et al. (22) found that a 5 µm filter significantly reduced the incidence of post-infusion phlebitis ($p < Ø,Ø1$). This was attributed to removal of particulate matter. Two of twenty-four patients (8%) developed phlebitis in the filter group, compared with 14/25 (56%) in the control group. Phlebitis was recorded if two or more of the following criteria were met over the 72 hour period of this double-blind study : erythema, induration, heat, erythematous streak and discomfort.

A recent study by Allcutt et al. (23) using a Ø,2 µm filter showed that, whilst the ultimate incidence of phlebitis was similar in the filter (48%: 49/1Ø1 infusions) and control groups (55%: 51/93 infusions), the filter significantly delayed the onset of phlebitis ($p < Ø,Ø1$). The incidence of phlebitis prior to 72 hours was 31% and 51% for the filter and control group, respectively. Phlebitis was recorded if inflammation was present. This study differs from others because no time limit was set on the length of infusion.

Five published studies (17,24,25,26,27) show no advantage for Ø,45 µm filters as regards post-infusion phlebitis. A

more recent double-blind study by Maddox et al. (28), using a Ø,22 µm filter and larger numbers than in the previous study by Maddox et al. (2Ø), confirms this lack of advantage for the filter group.

Collin et al. (24) recorded phlebitis, if the vein was inflamed for a distance of over 2 cm from the site of cannulation, in 39% of patients receiving filtered solutions compared to 44% in the control group. Filters were changed at 48 hourly intervals, or when the filter blocked; 45/84 filters required replacement in under 48 hours due to blockage.

Swift et al. (17) found there was no statistically significant difference between patients with final filters and those in the control group, as regards the occurrence of phlebitis and changes in temperature, pulse rate and diastolic blood pressure. Filters were changed daily during the 72 hour study.

O'Brien et al. (25), in a study of 48 patients over 48 hours, found the incidence of phlebitis to be 42% in the filter group and 4Ø% in the control group. The filters and cannulae were examined microbiologically after use, and found to be free of microbial contamination.

In the study by Chamberland et al. (26), a total of 1Ø7 infusions with filters (from 49 patients), and 84 infusions without filters (from 4Ø patients), gave a phlebitis rate of 67% in the former group and 63% in the latter, as judged by

the presence of tenderness and/or oedema.

Thayssen et al. (27), in their controlled double-blind study using a Ø,45 µm filter, found that the frequency of phlebitis was 47% (27/57) in the filter group and 57% (33/58) in the control group. The average duration of infusion was 4Ø hours in the former and 39 hours in the latter group. The filters were not changed during the study period, and 7 of the 57 filters used became blocked.

The incidence of post-infusion phlebitis in the filter group (38/95) and the control group (39/1ØØ) was also not significantly different in the recent study of Maddox et al. (28) using a Ø,22 µm filter in-line.

In another study, in which patients received total parenteral nutrition through in-line filters, the incidence of sepsis was four times greater than in the control group. This was attributed to the increased number of manipulations of the infusion system when filters blocked (29).

1.2.3 Microbial contamination

Micro-organisms can cause serious infection if they are allowed to enter and proliferate in the intravenous cannula wound or intravenous fluid. In addition post-infusion phlebitis may be due to bacterial contamination of cannula tips (6,8).

1.2.3.1 Contamination of cannulae

Cannulae become contaminated when inserted under non-sterile conditions, when the wound site becomes infected, or when contaminated solutions are administered, see Figure 1.1 (5).

Cannula-related infections derive mainly from the patient's own skin flora or from micro-organisms present on the hands of personnel inserting the cannula (30,31).

Micro-organisms gain access to the tip of the cannula at the time of insertion, and subsequently by migration along the interface between the cannula and surrounding tissue (32). Once contaminated, the cannula and its adherent thrombus serve as an intravascular nidus for the dissemination of micro-organisms.

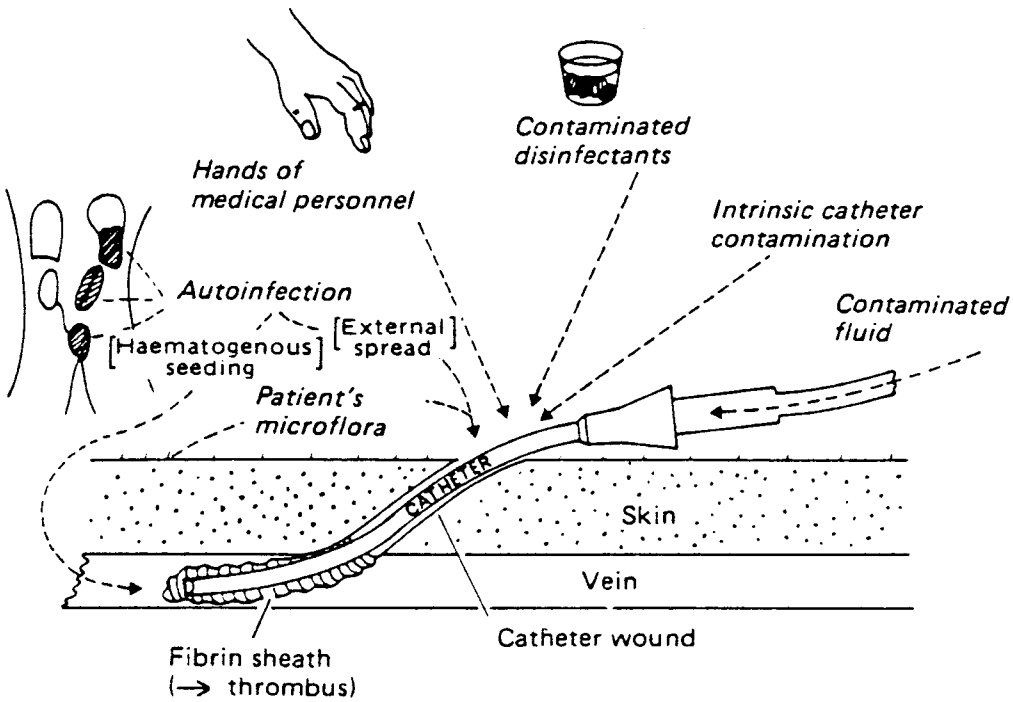
The most common isolates from cannula tips have been Staphylococcus aureus, Staphylococcus epidermidis, Gram-negative bacilli (especially Enterobacter, Escherichia, Klebsiella, Pseudomonas and Serratia species), Enterococci and Candida (8,13,31,32,33).

Cannula-related infections are frequently preceeded by, or associated with, phlebitis and can progress to suppurative phlebitis and systemic sepsis.

Most studies have shown no correlation between phlebitis and a positive cannula culture for micro-organisms. For example, 47% of 135 patients developed phlebitis in Cheney

Figure 1.1

Sources of intravenous cannula-related infection



(With permission D G Maki (5) and MTP Press)

and Lincoln's study, but only 9,7% had positive cannula tip cultures (34). In another study (35), 30% of 54 patients developed phlebitis and 40,7% of cannula cultures were positive, but there was no correlation between the two. Cannulae *in situ* for less than 48 hours were culture-negative, whereas 52% of those *in situ* for over 48 hours were culture-positive.

In the study by Collin *et al*. (24) on in-line filters, 55% (16/29) of the filter group had positive cannula tip cultures, as compared to 61% (14/23) in the control group. These investigators found no correlation between the presence of phlebitis and a positive cannula tip culture. Maddox *et al*. (28) also found that positive cannula tip cultures occurred as frequently in patients without filters as in those with filters.

Twenty one of 39 cannulae were contaminated in Baird and Doery's study (36); 19 with Gram-positive cocci, 1 with Gram-positive bacilli and 1 with both. Daily observations were made of the cannulation site in 21 patients; only 3 patients experienced tenderness or inflammation at the cannulation site, but 9 had contaminated cannula tips.

A prospective clinical study of 790 infusions by Band and Maki (37) also found no correlation between phlebitis and culture-positive cannula tips. An incidence of 40,2% phlebitis, 4,3% positive cannula cultures, and 0,63% cannula related septicaemias was reported.

Fuchs (38) reported that phlebitis, and other complications of intravenous infusion therapy, predisposed to a positive cannula tip culture. However, only 5,1% (5/99) cases of phlebitis were associated with a positive cannula culture, as compared to 3,5% (14/401) in cases with no phlebitis.

Some published studies do indicate that phlebitis and other complications may be associated with contaminated cannulae.

Maki et al. (39) found that cannula-related infection was associated with local inflammation. Of 250 cannulae cultured, 70,4% were culture-negative, 19,6% had a low level of contamination (ie they were culture-positive in broth culture or yielded 1-7 colonies on a plate culture) and 10% yielded significant growth on a plate culture. Four of the 25 cannulae in the latter group were associated with septicaemia and 16/25 (64%) with local inflammation; in comparison, 13,3% (30/225) of the remaining cannulae were associated with local inflammation.

Collins et al. (40) reported that 43% of cannulae removed from patients with phlebitis were culture-positive, and Collin et al. (15) that 61% of cannulae removed from patients with phlebitis were culture-positive. In the latter study 44% of cannulae, from patients not developing phlebitis, were culture-positive.

Smallman et al. (8) in 1980 reported that phlebitis developed in 34,5% of cannulations, in which an aseptic technique was used for inserting the cannula, and that 50%

of cannulae were culture-positive. In contrast, phlebitis developed in 100% of cannulations in the control group and 86% of cannulae were culture-positive. Staphylococcus epidermidis was most commonly cultured; Staphylococcus aureus, Micrococcus and Acinetobacter were also isolated. The duration of cannulation was 3,2 days in the former group and 3,4 days in the latter group.

Published studies do however indicate that patients with a positive cannula culture have a significantly increased risk of septicaemia (5,32). From a survey of 33 papers by Maki et al. in 1973 (32), the percentage of positive cultures from cannulae was found to vary from 3,8 to 57%, with rates of associated sepsis ranging from zero to 8%. In a more recent survey, a sepsis rate of Ø,5% (36/7618 infusions) was reported and 17,9% (543/3Ø31) of cannulae were contaminated following peripheral percutaneous cannulation (41).

Another survey of 916 cannulations (5) clearly demonstrated that the longer the duration of cannulation at one site, the higher the incidence of culture-positive cannula tips and associated septicaemia. On day one 11,2% of cannulae were culture-positive compared to 33,3% on day four; the incidence of septicaemia increased from zero on day 1 to 2,9% on day 4. With cannulations exceeding 48 hours, the incidence of cannula-related septicaemia has ranged from 0-8%, with an average of 2% (32).

In 1958, Moncrief (42) reported 4 cases of septic thrombophlebitis with fatal septicaemia and noted an

association between the incidence of complications and the duration of cannulation.

Septic phlebitis is the most serious form of cannula-related infection (5,13,43) and occurs almost exclusively with plastic catheters left *in situ* for longer than 48 hours. The vein becomes an intravenous abscess discharging organisms into the bloodstream.

The incidence of suppurative phlebitis following percutaneous cannulation has been estimated to be 0,2% (41).

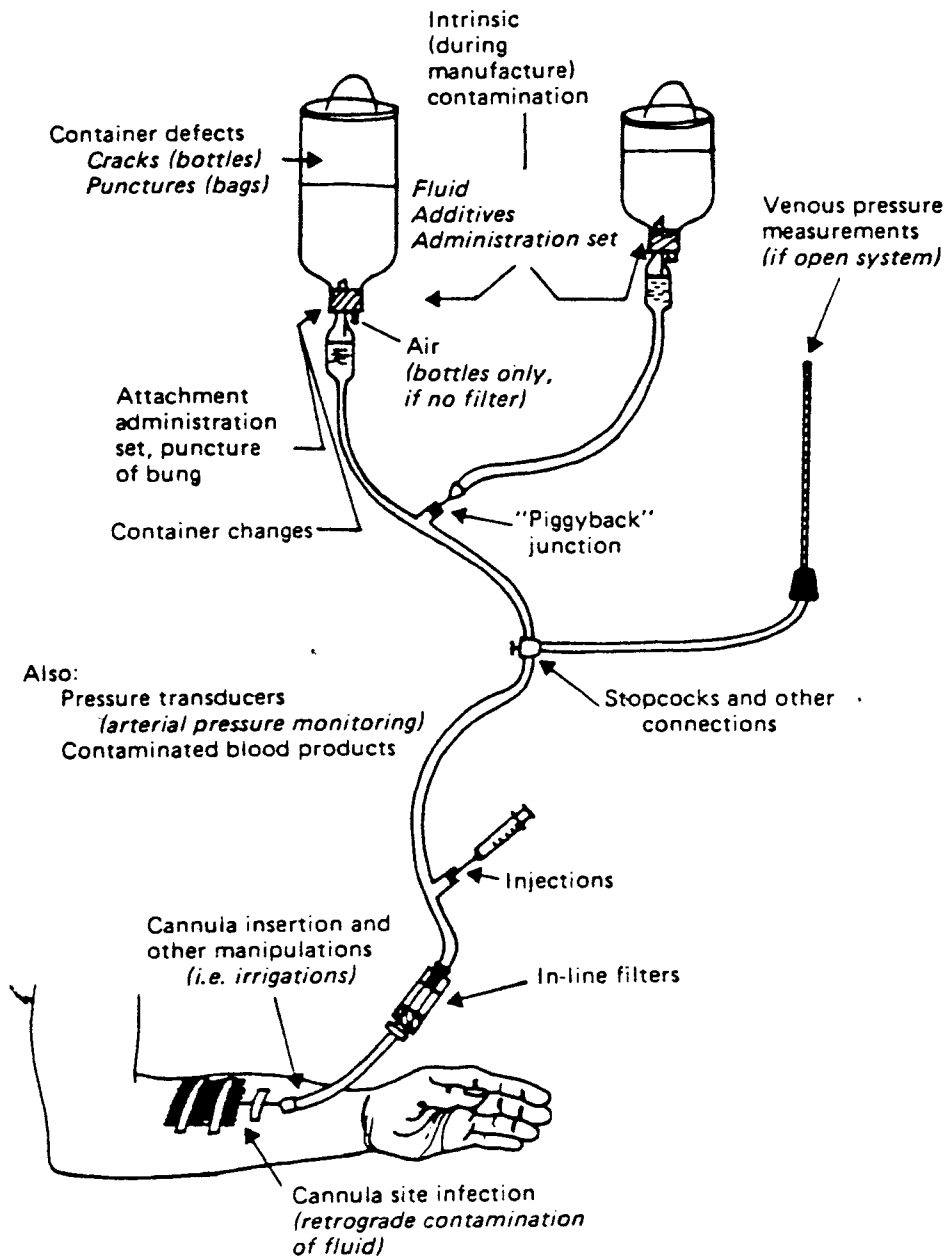
1.2.3.2 Contamination of infusion fluids

Infections related to microbial contamination of the infusion fluid occur less commonly than cannula-related infections, but often have more serious consequences (5,37,44).

Contamination of intravenous fluids can occur during manufacture, which is referred to as intrinsic contamination, or during administration to the patient, which is referred to as extrinsic contamination. Intrinsic contamination, arising before the fluid is used, is potentially more serious and has produced large scale epidemics of septicaemia, often resulting in death. Extrinsic contamination is usually seen on a smaller scale. The sources of contamination of infusion fluids have been illustrated by Maki, as shown in Figure 1.2 (5).

Figure 1.2

Potential sources for contamination of infusion fluid



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From a survey of world literature published between 1965 and 1978, Maki (31) found that 33 out of 97 epidemics of hospital-acquired bacteraemia were due to infusion therapy. Twenty eight epidemics were traced to contaminated infusion fluids. Contamination of infusion fluids during manufacture was implicated in 7, and in-use contamination in the remaining 21 epidemics.

The first reports of adverse reactions to contaminated infusion fluids appeared in 1953. O'Hare et al. (45) reported a fatal case of anaphylactic shock following the intravenous infusion of 10% m/v dextrose solution contaminated with Enterobacter aerogenes, and Michaels and Ruebner (46) attributed 2 cases of coliform septicaemia to contaminated infusion fluid. The significance of these reports was not appreciated until the early 1970's, when other cases were published.

In 1970, two reports implicated in-use contamination of infusion fluid with infection. Robertson (47) found two bottles of in-use dextrose in saline infusion fluid to be contaminated with fungi, one with Trichoderma and the other with Penicillium species, which they presumed to have gained access via cracks in the bottles. One patient developed transient fungaemia due to Trichoderma.

Sack (48) reported 5 cases of septicaemia following infusions from a bottle containing succinylcholine in 5% dextrose solution and from which Klebsiella pneumoniae and Enterobacter cloacae were subsequently cultured.

Contamination via a crack in the bottle was hypothesised following a subsequent sixth case.

Duma et al. in 1971 (49) reported 4 cases of septicaemia with in-use infusion fluid contaminated by organisms identical to those isolated from blood cultures. The infecting species of organism was Escherichia in two patients, one of whom died, Klebsiella in the third and Serratia in the fourth.

The widespread hazard of contaminated infusion fluids was first appreciated in the early 1970's when over 400 cases of Enterobacter septicaemia and 40 deaths, caused by intrinsic contamination of intravenous fluids, were reported from 25 hospitals in the United States. Half of the patients developed infusion phlebitis; this suggests that phlebitis can be caused by contaminated infusion fluids. This epidemic was traced to intrinsic contamination of a newly introduced, elastomer-lined, screw-cap closure (2).

Another epidemic began in 1971 in a London hospital. Forty patients developed infection from deionised water, containing Pseudomonas cepacia, which contaminated closures and bottles of infusion fluid when used in the rapid cooling autoclave (50).

Other cases of septicaemia due to Enterobacter species occurred in 1972 in a hospital near Plymouth, England. Six patients died after receiving 5% dextrose solution contaminated with Gram-negative bacteria, including

Enterobacter agglomerans and Klebsiella aerogenes. Contamination was traced to faulty autoclaving equipment at the manufacturer's plant (51,52).

In another outbreak, 5 patients developed sepsis from contaminated 5% dextrose in lactated Ringer's solution. Citrobacter freundii was recovered from the blood of 3 patients, Enterobacter cloacae from the fourth and Enterobacter cloacae plus Enterobacter agglomerans from the fifth (32).

Infections due to contaminated infusion fluids are almost exclusively due to Gram-negative bacilli, primarily Klebsielleae tribe (Klebsiella, Enterobacter and Serratia species) although Citrobacter freundii and Pseudomonas cepacia have also been implicated in epidemics (31). These organisms are able to proliferate in dextrose-containing intravenous fluids; most other organisms die or are unable to proliferate in such fluids (30).

Many studies have shown that even if an infusion fluid is sterile on arrival at the hospital ward it may become contaminated with micro-organisms during administration. Table 1.1 gives some documented examples of in-use contamination rates and the contaminants found in infusion fluids.

TABLE 1.1

Studies of in-use contamination rates and microbial contaminants present in intravenous infusions.

Reference		Number of samples	% Contamination	Micro-organisms isolated
Wilmore & Dudrick	1969(19)	250*	2,8	-
Deeb & Natsios	1971(53)	236	3,8	Alcaligenes faecalis Escherichia coli Klebsiella-Enterobacter Staph. epidermidis
Duma et al.	1971(49)	68	35,0	Candida sp Bacillus sp Corynebacterium sp Enterobacter sp Escherichia sp Flavobacterium sp Mima sp Klebsiella sp Pseudomonas sp Serratia sp Staph. epidermidis Streptococcus sp
Letcher et al.	1972(54)	365	10,4	Candida sp Bacillus subtilis Corynebacterium sp Staph. epidermidis
Myers	1972(55)	43	14,0	-
		25	24,0	Bacillus subtilis Flavobacterium sp Staph. epidermidis
Collin et al.	1973(24)	80*	21,0	Anthracoids Corynebacterium sp Pseudomonas aeruginosa Staph. aureus Staph. epidermidis Strep. faecalis
D'Arcy & Woodside	1973(56)	101	39,0	-
Hughes	1973(57)	183	4,3	-
Lapage et al.	1973(58)	-	-	Acinetobacter lwoffii Citrobacter freundii Citrobacter koseri Citrobacter sp Corynebacterium sp Enterobacteriaceae Enterobacter agglomerans Enterobacter cloacae Klebsiella sp Klebsiella aerogenes Pseudomonas sp Pseudomonas cepacia
Hanson & Shelley	1974(59)	76	5,3	Bacillus subtilis
Maki et al.	1974(60)	94	11,0	Bacillus sp Escherichia coli Klebsiella pneumoniae Micrococcus sp Staph. aureus Staph. epidermidis
Newman et al.	1975(61)	72*	27,0	Bacillus sp Chromobacterium sp Micrococcus sp Staph. aureus Staph. epidermidis
Woodside et al.	1975(62)	1003	4,4	Gram-negative rods Staphylococcus sp Streptococcus sp
Rusmin et al.	1977(63)	65*	11,0	Bacillus sp Citrobacter sp Corynebacterium equi Pseudomonad Staph. aureus Staph. epidermidis
Band & Maki	1979(37)	790	0,63	Bacillus sp Enterobacter cloacae Enterococcus sp Klebsiella pneumomiae Staph. epidermidis
Bernick et al.	1979(64)	63	3,0	-
Buxton et al.	1979(65)	600	2,0	Candida albicans Escherichia coli Enterobacter cloacae Proteus mirabilis Pseudomonas paucimobilis Staph. epidermidis
Baird & Doery	1981(36)	415	5,1	Yeasts Corynebacterium sp Gram-positive rods Staphylococcus sp Streptococcus sp

1.2.4 Particulate contamination

Concern about the quantity of particulate matter in intravenous solutions, improvements in filtration techniques and the introduction of quantitative quality control regulations, in the British Pharmacopoeia 1973 (66), has led to a considerable reduction in the level of particulate matter in infusion solutions.

However, the final solution entering the patient may be heavily contaminated with particulate matter introduced from the giving set, syringes, ampoules and intravenous additives (67,68).

The clinical consequences of particulate matter are unclear, however, granulomas (69,70) and phlebitis (3,16) have been observed after the infusion of particles. It is thought that the degree of danger may depend upon the number and size of particles, the physical properties of the particle, the biological properties of the particle, the final location of the particle in the vascular system and the host response to the particle (71). As each particle has the potential to cause an adverse effect (72), the probability of an adverse reaction is proportional to the total number of particles introduced (71,72).

Drews (73) was probably the first to realise the clinical implications of particulate matter in solutions. Drews found that patients with particles trapped behind a transplanted cornea experienced a visual haze and that the

irrigating solutions used during surgery contained from 435 to 958 particles per millilitre, in the size range 5 to 300 μm. Therefore, he recommended filtration of the solutions prior to use.

1.2.4.1 Animal studies

Dunn (74), in 1920, studied the effects of embolism of pulmonary arterioles following the intravenous administration of starch granules into animals. Large quantities decreased systemic arterial pressure, increased systemic venous pressure and produced death within 5-30 minutes. Dunn believed that the starch granules remained in the lungs.

Kittle et al. (75) produced pulmonary hypertension in dogs following the repeated intravenous injection of carborundum particles of 50-400 μm. The authors could not determine if the increased pulmonary artery pressure, after pulmonary embolization, was due to vascular obstruction or if an associated vasospasm had occurred. As the quantity of particles required to produce pulmonary hypertension was many times the quantity required to produce an acute lethal effect, this suggested that vasospasm might be partly responsible for death in acute embolization.

Stehbens and Florey (76) found that the introduction of particulate matter into the blood stream led to agglutination of platelets, to which the particles adhered, and a reduction in the number of platelets circulating in

the blood stream. White and red blood cells also adhered to these masses, and formed thrombi which frequently blocked capillaries.

Gesler et al. (77), in 1973, reported on the effects of injecting rats with varying quantities and sizes of inert polystyrene spheres. Thirteen of 18 rats injected with $8x10^6$ particles/kg 40 µm in size developed laboured respiration and died within 3-5 minutes of injection; another rat injected with $4x10^5$ particles/kg 4 µm in size died within 3 minutes of injection. All other rats injected with polystyrene particles or control vehicle were unaffected. Particles of 4 µm were found in the lung, liver and spleen of test animals, whilst those of 10 µm were found primarily in the lung, but also in the heart, liver, spleen, kidney, brain and pancreas. The authors concluded that nonreactive particles administered intravenously "...up to dosages that produced death were without clinical or tissue toxicity."

Other investigators have reported the presence of particles in organs such as the brain, liver, heart, spleen and kidney (69,78,79). Glass beads, up to 390 µm in diameter, can pass through the pulmonary capillary bed and reach the systemic circulation via arteriovenous shunts in the lung (79).

Dorris et al. (4) demonstrated that residues, obtained after filtration of 5% dextrose in water and sodium cephalothin solution, produced a reaction on the venous endothelium of rabbits. They noted venous congestion, perivenous

haemorrhage, and some necrosis after the infusion of particulate matter from dextrose solution. The changes following sodium cephalothin were more severe and included necrosis and degeneration of the vein wall. These authors also demonstrated, using dogs, that in-line filtration reduced the severity of the venous endothelial reaction to intravenous infusions.

Animal studies have shown that microspheres larger than 7,5 µm in diameter are localised in the capillary beds of the lungs during the first pass following intravenous administration, while microspheres smaller than 7,5 µm clear the lungs and accumulate primarily in the liver and spleen (77). If, however, a large particle bypasses the lungs, via arteriovenous shunts in the lung (8Ø), it might occlude an arteriole in the brain, kidney or eye and cause injury (69,71).

Several investigators have demonstrated that particulate matter in tissues leads to granuloma formation.

Wartman et al. (81) reported in 1951 that, following the injection of filter paper fibres into rabbits, emboli became impacted in the pulmonary arteries or adhered to the intima. In one rabbit an embolus adhered to the endocardium of the right ventricle, resulting in an acute inflammatory response which subsided after a week. The filter paper fibres were surrounded by foreign body granulomas and became localized in either the vessel wall intima, media or adventitia. The granulomas frequently extended through the walls of the

arteries, and were found also in the lung or in perivascular sites. The authors interpreted this as indicating the existence of a mechanism for ridding the circulation of foreign material in the blood.

Intravenous infusions in healthy rabbits resulted in the formation of capillary and arterial granulomas, containing fragments of cellulose fibres, in the lungs (69). The investigators estimated that for every 500 millilitres of intravenous fluid injected into each rabbit, there were 5000 granulomas scattered throughout the lungs.

Purkiss (82) injected cellulose fibres into 40 mice and saline into another 10 for control purposes. Granulomas were found in the lungs of all test mice, but not in the controls.

Lasker et al. (83) demonstrated, following peritoneal dialysis, the presence of particulate matter in inflamed peritoneal membranes of mice. The inflammation was prevented by filtration of the solutions through 0,22 or 0,45 µm filters.

1.2.4.2 Clinical significance of particulate matter

Turco (84) concluded in 1973, in his review of the clinical significance of particulate matter, that "Although the biological effects of particulates injected into humans are still undefined ... Particulate matter is an unwanted and unnecessary addition to medication therapy."

The clinical significance of particulate matter from intravenous solutions is still not clear. However, extrapolation from animal studies suggests that particles entering the systemic circulation may occlude a blood vessel directly, activate the formation of a thrombus, thus indirectly causing an occlusion, form granulomas, precipitate an allergic reaction or cause infusion phlebitis.

Particles are potentially harmful to the eyes, lung and brain. The lung acts as a filter trap for the venous circulation, but it is possible for particles to pass through or bypass the pulmonary capillary bed and then block a small arteriole in the kidney, eye or brain (69,71). Liebow et al. (85) and Hales (80) have shown that arteriovenous shunts exist in the human lung.

A 1966 United States Food and Drug Administration sponsored symposium concluded that particulate matter in parenteral drugs can result in pulmonary microemboli, thrombi or granulomas and reflex vasoconstriction in the lungs (86).

The chemical composition of the particle may be critical. It may be biologically inert, or incite an inflammatory reaction or, even worse, a neoplastic response by the host. The particle could also be antigenic and sensitize the patient to a future allergic reaction (71,87).

A foreign particle may initiate an inflammatory response in a blood vessel, and vascular granulomas caused by

particulate matter may also have deleterious effects on blood vessels and tissue (72,81,88).

Information on the clinical effects of parenteral injection of particles is sparse. Pulmonary embolism has been reported in 5 to 14% of all autopsies (89). The embolism is usually caused by a blood clot, but may also be caused by foreign particles (90).

Embolization of the lungs by particulate matter produces severe pulmonary hypertension, a fall in systemic blood pressure and death. Distension of the right cardiac chambers and engorgement of the peripheral veins develops, in conjunction with occlusion of the main pulmonary artery. It has been postulated that particulate embolism induces reflex pulmonary artery constriction, and this may explain the deaths of patients when pulmonary emboli block only a minor portion of the pulmonary artery bed (89).

In a study (91) of 173 patients undergoing cardiac catheterization and/or surgery, 14 (8%) had fibre emboli in routine autopsy sections. Fibres were found in the pulmonary, renal, cerebral, and mesenteric arteries. The embolized fibre often resulted in narrowing or occlusion of the involved vessel. This study associated 3 cases of infarction with embolic fibres. In one patient multiple foci of cerebral necroses were present, associated with fibre emboli, within small cerebral vessels. In another patient long fibres were present within a thrombus that occluded a major pulmonary artery, resulting in pulmonary

infarction. In the third case, fibres were present within a thrombus removed from the occluded radial artery of the patient, in whom ischaemia of the left hand developed 24 hours after the artery had been cannulated. The hand was subsequently amputated for gangrene necrosis.

Garvan and Gunner (69,70) examined postmortem sections of the lungs of terminally ill patients, who had received long term intravenous therapy. They found granulomas, similar to those in animals, and chronic fibrous pneumonitis; cellulose fibres and crystals were present in the fibrous tissue. Granulomas, caused by particles introduced into the cerebral circulation during angiography, were also observed in the brains of treated patients.

Garvan and Gunner (69) quote the autopsy results of other investigators who found pulmonary vascular granulomas, due to fibres, in children. The only common denominator was that all the children had received intravenous therapy.

These investigators also identified foreign particles lodged in the lungs of an infant who died after receiving 2700 millilitres of intravenous fluid (70).

It has been speculated that the adverse effect of particulate matter in intravenous solutions may be greater in patients who are hospitalized since they are often recumbent, with a resultant sluggish pulmonary circulation (72). In addition, these patients may be receiving therapy with corticosteroids or other agents which could so modify

tissue response that a granulomatous process, which would otherwise be localized, could extend through the lungs (72).

Woodhouse in 1980 (92) stated that phlebitis "...is an acute sterile inflammation without bacterial infection." Many clinical studies have failed to demonstrate any correlation between microbial contamination and the development of infusion phlebitis. This suggests that many cases of phlebitis may not be attributable to microbial infection.

If microbial contamination of cannulae or infusion fluids were the primary cause of infusion phlebitis, concomitant administration of antibiotics might be expected to reduce its incidence. This is not the case. On the contrary, antibiotic therapy itself has been shown to cause infusion phlebitis (93,94). Studies have revealed the presence of subvisible particulate matter in many antibiotic preparations (4,95,96,97), and this may partially explain their ability to cause infusion phlebitis.

1.2.4.3 Quantity and content of particulate contamination

Particles maybe introduced into intravenous solutions during the manufacturing process, from the administration apparatus, or from drug additives.

Draftz and Graf (98) in 1974 examined intravenous solutions of normal saline and 5% dextrose and found the main source of particles to be the rubber stopper. Flakes of lacquer

and salt crystals constituted 1-10% of the particles, and starch granules, glass, mica flakes and metal shavings less than 1%. The number of particles per litre, greater than 1 µm in size, ranged from 6 000 to 77 000 for saline and 10 000 to 32 000 for dextrose solution, whilst in the case of particles larger than 5 µm, the range was 1 000 to 13 000 and 2 000 to 6 000, respectively. Particles up to 100 µm in size were observed.

Winding and Holma (99) reported in 1976 that more than 250 000 particles in the size range 0,5-50 µm were present in 1 litre of infusion fluid.

Pearse et al. (100) in 1982 reported particle counts, per litre of intravenous fluid, of 20 000 to 72 000 for particles over 2 µm, and 5 000 to 16 000 for particles over 5 µm, using a Coulter Counter. These fluids, however, do comply with the British Pharmacopoeia 1980 (101) requirement that intravenous fluids should contain not more than 1 000 particles per ml greater than 2 µm, and not more than 100 particles per ml greater than 5 µm when using an apparatus such as the Coulter Counter.

Myers (55), from a study using 0,45 µm end-line filters, estimated that a patient may receive between 100 000 and 2 million particles greater than 1 µm during intravenous fluid therapy, depending on the number of bottles of fluid infused. The particles identified on the filters included fibres of paper, cotton and flax (400 µm in length), glass and plastic.

Davis and Turco (67) reported in 1971 that 50-70% of infusion systems contained additives, which could increase the particle count many fold. Schroeder and DeLuca (97) estimated that a patient given intravenous therapy, including antibiotics, could receive with each litre of fluid 34 000 particles larger than 5 µm, 1 400 particles larger than 10 µm and 500 particles larger than 25 µm.

Illum et al. (102) found administration sets to be a serious source of particulate contamination. Some particles released from the sets were larger than 100 µm.

Mehrkens et al. (68) estimated that the total number of particles a patient might receive, during 24 hours of infusion therapy, to be 1 920 504. The particulate matter was introduced from the following sources:

Infusion solutions (3000 ml)	353 189	particles
Additions of medicines	1 285 189	particles
Ampoules	216 350	particles
Latex fitment	24 776	particles
Syringes	41 000	particles
	1 920 504	particles

Pearse et al. (100) in 1982 recommended, following particle counts on intravenous medicines, that certain additives, especially powders requiring reconstitution, should be filtered during aseptic addition to intravenous fluids. These drugs included chloramphenicol, cephazolin, oxytocin, aminophylline and aminophylline in combination with

hydrocortisone. The particle counts of intravenous fluids, to which drugs had been added without prior filtration, are given in Table 1.2 (100).

Table 1.2

Particle content of intravenous fluids to which drugs had been added without filtration, determined using a Coulter Counter

Intravenous fluid	Additive	Particles/ml ≥2 µm	≥5 µm
Dextrose 5% 100ml	Chloramphenicol 1g	1 075	23
Dextrose 5% 100ml	Erythromycin 1g	213	36
Dextrose 5% 500ml	Naftidrofuryl 200mg	67	4
Dextrose 5% 500ml	Oxytocin 10 IU	649	140
Dextrose 5% 500ml	Aminophylline 250mg +hydrocortisone 100mg	4 623	776
Sodium chloride 0,9% 100ml	Benzylpenicillin 1mu	95	6
Sodium chloride 0,9% 100ml	Cephazolin 1g	1 060	66
Sodium chloride 0,9% 100ml	Cimetidine 200mg	71	8
Sodium chloride 0,9% 100ml	Flucloxacillin 500mg	81	6
Sodium chloride 0,9% 500ml	Aminophylline 250mg	1 630	237
Sodium chloride 0,9% 500ml	Aminophylline 250mg +hydrocortisone 100mg	10 364	2 812
Sodium chloride 0,9% 500ml	Heparin 5000 u	37	4
Sodium chloride 0,9% 500ml	Hydrocortisone 100mg	52	6
Sodium chloride 0,9% 500ml	Parentrovite	51	10

From Pearse et al. (100)

1.3 Aims and scope of study

This review of the literature clearly shows that, whilst every care may be taken during manufacture to ensure that the patient receives particle free, sterile intravenous infusion fluids and medicines, the possibility of contaminants entering the system during use and causing associated problems, is always present.

This project was undertaken with the following aims:

1 To determine if the addition of an in-line filter to the infusion set reduces the incidence of phlebitis. This is deemed important because of the discrepancies between published reports and also because, in the majority of studies showing an advantage for filters, the filters were not changed daily as is now recommended.

2 To determine the level of microbial contamination of infusion systems by culturing the filters and identifying the micro-organisms isolated.

3 To determine, in view of the controversy in the literature, whether there is any correlation between phlebitis and culture-positive cannula tips and whether filters reduce the incidence of contamination of cannula tips.

4 To determine particle counts in the commonly used intravenous infusion fluids and medicines, and to

establish whether there is any correlation between particulate contamination and phlebitis.

CHAPTER 2

CLINICAL STUDY OF A Ø,2 µm IN-LINE FILTER

2.1 Aim

This aspect of the investigation was aimed at determining whether the complications of intravenous infusion of fluids and additives might be reduced by the inclusion of a Ø,2 µm air venting final filter in-line. The filter effectively removes microbial and particulate contaminants above Ø.2 µm from intravenous fluids and additives.

2.2 Location

The clinical study was carried out in the Medical, Surgical and Gynaecological Wards at Groote Schuur and New Somerset Hospitals. Haematological studies were carried out in the Haematology Departments at these hospitals.

2.3 Patient selection

Patients belonging to either sex and any racial group, aged from 12 to 7Ø years, and anticipated to require intravenous infusions via a peripheral line for 48 hours or longer, were included in the study. Diabetic patients and patients receiving blood, fat emulsion, 5Ø% dextrose solutions or high molecular mass dextrans were excluded from the study.

2.4 Study design

Patients were allocated at random to either the filter or control (filter not included in the access line) group by the trial sister prior to cannulation. The filter was attached to the distal end of the infusion set, immediately prior to cannulation, by the trial sister or the physician in-charge and primed with intravenous infusion fluid (see Appendix I). Cannulation was carried out according to the procedure normally used by the physician, no attempt being made to prevent variations due to personnel changes in order to evaluate the practical benefit of filters in everyday use, and the filter outlet was connected to the cannula. Tetrafluoroethylene cannulae of varying size, as specified in Table 2.1, were used.

The filters were changed daily, using the aseptic technique detailed on page 65, by the trial sister and retained for microbiological evaluation. The infusion sets were changed in accordance with the normal procedure of the hospital concerned. Cannulation site changes were carried out as directed by the physician in-charge. The cannula was removed by the trial sister, except for inadvertent removal by ward staff or patients, using the procedure outlined on page 68, and retained for microbiological evaluation.

Patients on prolonged intravenous therapy were included for more than one cannulation site. Subsequent allocation to the filter or control group was random.
Patient details were recorded as specified in Appendix II.

2.5 Patient assessment

The trial was observer-blind. Patients were assessed daily for phlebitis, by the investigator, for the period of cannulation and upon removal of the cannula, using the following criteria based on those suggested by Maddox et al. (20):

Severity	Criteria
Ø	No pain or tenderness at the intravenous site, no erythema, no swelling, no induration, no palpable venous cord
1+	Painful or tender intravenous site, no erythema, no swelling, no induration, no palpable venous cord
2+	Painful or tender intravenous site with erythema or some degree of swelling, or both, no palpable venous cord
3+	Painful or tender intravenous site with erythema and swelling and with induration or a palpable venous cord less than 7 cm above the cannulation site
4+	Painful or tender intravenous site, erythema, swelling, induration and a palpable venous cord greater than 7 cm above the cannulation site
5+	Frank vein thrombosis together with all the signs of 4+; the infusion may have stopped running due to thrombosis

Phlebitis was considered to be present if a score of 2+ or

more was recorded.

The following parameters were also monitored prior to the initiation of intravenous therapy and, thereafter, at daily intervals:

1) Body temperature (sublingual)
2) Pulse rate
3) Respiratory rate
4) Blood pressure
5) Erythrocyte sedimentation rate
6) White blood cell count
7) Haemoglobin and haematocrit

The length of infusion and time to the discovery of phlebitis was recorded to the nearest hour. The reason for termination of each infusion was recorded as being one or more of the following:

a) elective
b) development of phlebitis
c) blockage
d) infiltration into tissues
e) inadvertent removal by patients or ward staff.

2.6 Medication

Full details of intravenous fluids and all medication were recorded, and these are given in Appendix 11. Intravenous antibiotics were administered over 3Ø minutes, using an Add-A-Line, piggy-back to the infusion fluid. The

preparation of antibiotics, in minibags containing 50 ml normal saline, was carried out by the ward sister. Intravenous potassium chloride and vitamins were added directly to the infusion fluid.

Infusion fluids were supplied in plastic containers except for Plasmolyte B®, which was supplied in glass bottles.

Drugs administered in concentrations of less than 5 µg/ml, or in doses of less than 5 mg over a 24 hour period were not passed through the filter (103).

2.7 Statistical analysis

Preliminary statistical analysis was carried out using either the chi-square test or the Student's t test (104). The chi-square test or Fisher's two-tail test of exact probability (104) were used to determine the independence of concomitant variables which could possibly affect the incidence of phlebitis.

Continuous variables were compared using the Student's t test. When an equivalent nonparametric method was required, either the Kruskal-Wallis one-way analysis of variance by ranks or the Wilcoxon two-sample test was used (105).

The Kaplan-Meier estimate of survival function was used to compare the filter and control groups with regard to time for the development of phlebitis, because the data were censored, ie the infusions were not all continued until

phlebitis developed. The significance of the difference between the two groups was determined using Gehan's test (106).

The null hypothesis was that there is no statistically significant difference in parameters between the filter and control groups. Significance was assigned to a probability value of less than 0,05; where an association is reported as not statistically significant, this indicates a probability value of greater than 0,05.

Infusions discontinued prior to 30 hours due to blockage of the access line or infiltration into tissues were not included in the final statistical analysis (unless phlebitis had already developed), as studies have shown a low incidence of phlebitis under 30 hours (10,65).

To test the randomization procedure and the comparability between the filter and control groups, the patient's age was examined by analysis of variance.

Chi-square analysis of each of the following categorical variables versus treatment group was performed: sex, cannula size, cannulation site, medical condition, surgical procedure, type of intravenous fluid, addition of intravenous potassium chloride, antibiotics, other medicines, smoking habits, alcohol intake, reason for discontinuation of the infusion, and whether the infusion was an initial or subsequent infusion.

2.8 Results

Patient data and results are detailed in Appendix II. Patients included in the final statistical analysis were numbered consecutively from ØØ1 and patients not included in the final statistical analysis were numbered consecutively from 1Ø1. Hence, the first 3 digits of each Trial Number refer to the patient number and the digit after the oblique indicates the Trial cannulation site number.

One hundred and nine patients, aged 13 to 66 years, were included in the study which was conducted over a period of six months. Twenty eight patients were excluded from the final statistical analysis for the reasons given in Appendix III. The 81 remaining patients yielded results for 132 infusions, 41 patients having more than one cannulation site included in the study. A total of 62 infusions was studied in the filter group and 7Ø in the control group.

The filter and control groups were comparable with respect to all the parameters in Table 2.1. No significant difference was found between these parameters in the two groups.

Other variables such as oral and intravenous medication, type of cannula, smoking habits, alcohol intake, surgical procedure and medical condition were also tested using the chi-square test and no significant differences between the groups were found. Table 2.2 lists the surgical procedures and medical conditions in the two groups and Tables 2.3 and

Table 2.1

Comparison of patient data in the filter and control groups

Parameter		Filter Group n=62	Control Group n=70
Mean age (years)		35,9	38,5
Sex	male	48	58
	female	14	12
Race	white	1	1
	black	25	28
	mixed	36	41
IV infusion fluids*	Dextrose 5%	8	6
	Maintelyte®	16	16
	Normal saline	51	56
	Plasmolyte B®	0	5
	Rehydration fluid	5	2
Cannula size	16 gauge	1	3
	18 gauge	31	31
	20 gauge	30	32
	Not recorded	0	4
Cannulation site	Basilic vein	10	14
	Cephalic vein	40	44
	Cubital vein	2	1
	Dorsal vein	8	7
	Radial vein	0	2
	Other	2	2

* More than one type of infusion fluid was used in 28/132 infusions.

Note:

The Student's t test was used to compare age, and the chi-square test was used to compare all other parameters in the filter and control groups. No differences were found at the p=0,05 level of significance.

Table 2.2

Surgical procedures and medical conditions in the filter and control groups

Patient data	Filter Group n=62	Control Group n=70
Surgical procedure		
abdominal	2	5
drainage of lung abscess	1	0
repair of pneumothorax	0	1
drainage of septic wound	1	0
Medical condition		
bacterial endocarditis	4	4
cardiovascular disease	1	3
collagen disease	0	1
gynaecological disorders	2	1
lymphoma	1	1
lung disorders	6	9
meningitis	4	3
multiple pathology	3	4
pancreatitis	1	0
pneumonia	34	34
renal disorders	2	4
septicaemia	1	1

Note

1) Surgical procedures and medical conditions were grouped together for statistical purposes.

2) The patient details referred to in the various categories above are given in Appendix II.

3) One patient in the filter group (Patient Number 001) and one in the control group (Patient Number 042) had both a surgical procedure and a medical condition.

2.4 the oral and intravenous medicines, respectively that were administered.

The majority of patients had an infection, most commonly pneumonia, and therefore antimicrobial agents were the most common medicines administered intravenously, penicillin and/or a cephalosporin being the usual drugs of choice (Table 2.4). The most common oral medicines administered were analgesics, non-steroidal anti-inflammatory agents, and antimicrobial agents; metronidazole was the most frequently used antimicrobial agent (Table 2.3).

Of the 132 infusions analysed, 74 (56%) resulted in the patient developing post-infusion phlebitis of grade 2+ or greater. In the filter group 29/62 infusions (47%) resulted in phlebitis, as compared to 45/70 (64%) in the control group (Table 2.5). This difference was significant at the 5% level, using the chi-square test (p=0,0431). A significant reduction in the incidence of phlebitis, between the control and filter group, was also found at 48 hours (p=0,005) and 72 hours (p=0,0062), but not at 30 hours, using the chi-square test.

The mean time to phlebitis was 77,1 hours for the filter group and 63,3 hours for the control group, and the mean duration of infusion was 75,9 hours for the filter group and 85 hours for the control group.

Due to the non-normal distributions of time to phlebitis and duration of infusion, the filter and control groups were

Table 2.3

Oral medicines administered

Medicines	Filter Group	Control Group
Analgesics		
Acetylsalicylic acid	5	3
Dextropropoxyphene	2	5
N S A I's	12	12
Paracetamol	12	13
Antimicrobial agents		
Amoxycillin	Ø	3
Co-trimoxazole	1	Ø
Erythromycin	1	Ø
Metronidazole	13	12
Tetracyclines	Ø	1
Antituberculous agents	2	1
Cardiac and Respiratory agents		
β receptor stimulants	4	8
Digoxin	2	3
α Methyl dopa	Ø	1
Nitrates	1	1
Prazosin	2	4
Solphyllin*	1	Ø
Corticosteroids	1	1
Diuretics		
Furosemide	4	7
Moduretic°	3	5
No. of medicines		
Ø	15	14
1	17	17
2	12	19
3	10	10
4	6	6
5	1	3
6	Ø	Ø
7	Ø	Ø
8	1	1

key

*Solphyllin® - each 15 ml dose contains Theophylline 80 mg
Etofylline 10 mg

°Moduretic® - each tablet contains
Amiloride Hydrochloride 5 mg
Hydrochlorothiazide 50 mg

N S A I's Non-steroidal anti-inflammatory agents

Table 2.4

Intravenous medicines administered

Medicines	Filter Group	Control Group
Antimicrobial agents		
Aminoglycosides	15	9
Ampicillin	1	Ø
Cefamandole	2Ø	24
Ceftazidime	8	7
Chloramphenicol	3	3
Erythromycin	Ø	1
Metronidazole	3	1
Penicillin	3Ø	33
Tetracyclines	1	3
Others		
Aminophylline	Ø	4
β receptor stimulants	Ø	1
Clothiapine	Ø	3
Diazepam	Ø	1
2'-Deoxycoformycin	Ø	1
Furosemide	Ø	2
Heparin	Ø	1
Hydrocortisone	1	1
Methylprednisolone	Ø	1
Morphine	2	Ø
Potassium Chloride	5	3
Vitamin B Compound	2	1
No. of medicines		
Ø	4	2
1	32	43
2	16	16
3	8	3
4	1	4
5	Ø	Ø
6	Ø	2
7	1	Ø

Table 2.5

Cumulative incidence of phlebitis over time in the filter and control groups

Duration of infusion (h)	Cumulative incidence of phlebitis Filter group n=62		Control group n=70		p*
<30	3	(5%)	10	(14%)	>0,05
30-48	9	(15%)	25	(36%)	0,005
48-72	15	(24%)	33	(47%)	0,0062
>72	29	(47%)	45	(64%)	0,0431

* Differences were tested using a chi-square analysis; significance was assigned to a probability value of 0,05.

Table 2.6

Severity of phlebitis in the filter and control groups

Phlebitis grade	Filter group n=62		Control group n=70		p*
0	21	(34%)	18	(26%)	>0,05
1+	12	(19%)	7	(10%)	>0,05
2+	18	(29%)	21	(30%)	>0,05
≥3+	11	(18%)	24	(34%)	0,0316

Differences were tested using a chi-square analysis; significance was assigned to a probability value of 0,05.

compared with regard to these variables using a nonparametric method of analysis. The Kruskal-Wallis one-way analysis of variance showed no significant differences between the filter and control groups as regards mean time to phlebitis and mean duration of infusion.

Table 2.5 and Figure 2.1 show that the incidence of phlebitis increased with time.

The probability of not developing phlebitis as a function of time was compared for the filter and control groups. Since many of the observations were censored, the method of Kaplan and Meier (the K-M estimate of the survival function) was used. Figure 2.2 depicts these estimates for the filter and control groups and shows that the incidence of phlebitis was lower in the filter group between 25 and 130 hours.

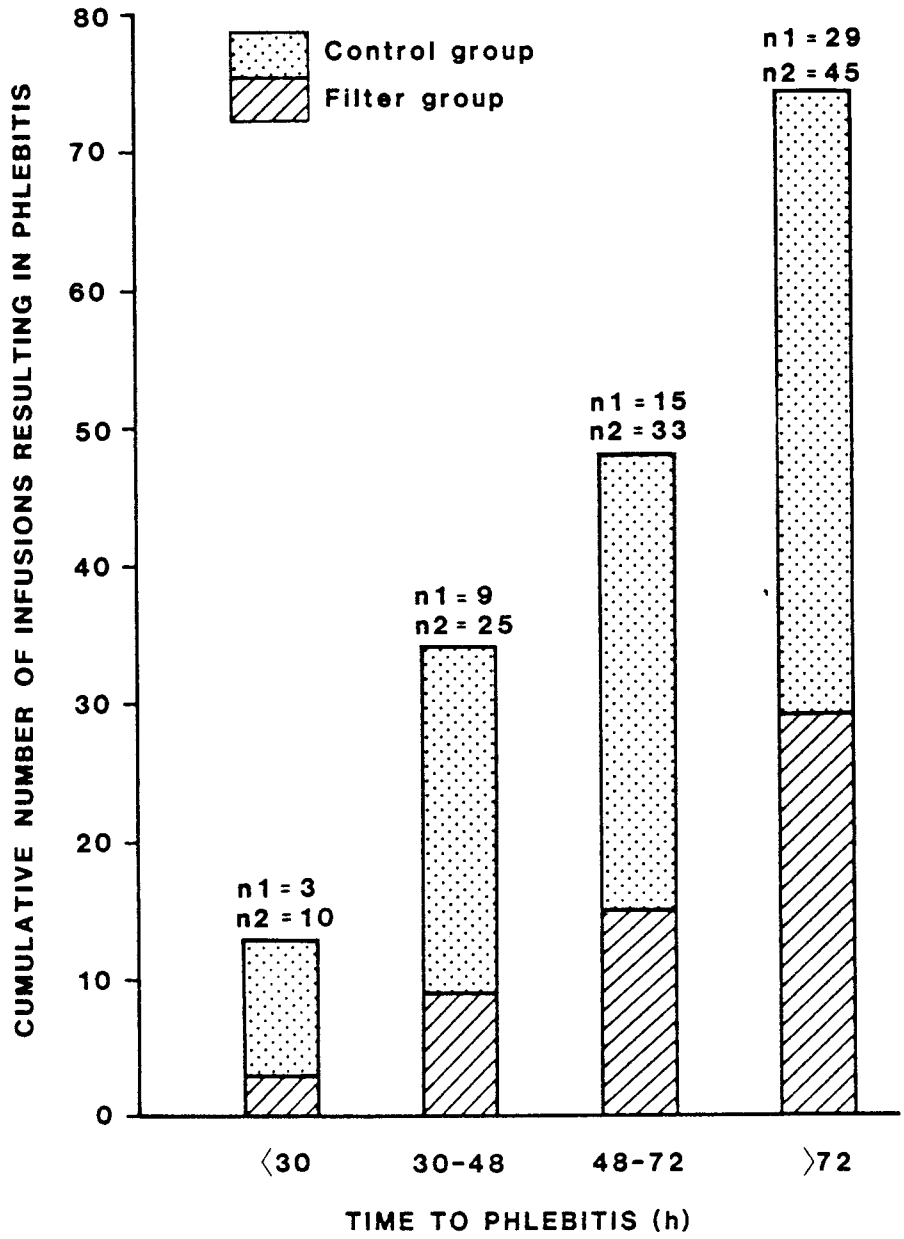
The significance of this difference was tested using Gehan's test which is a generalisation of Wilcoxon's rank test. The generalisation was necessary due to the use of censored data. A test statistic of 2,25 was obtained, which is significant at the 5% level.

Gehan's test was also used to compare the incidence of phlebitis between initial and subsequent infusions. No significant difference was found.

The chi-square test was used to investigate whether cannula size or site of cannulation affected the incidence of phlebitis. Neither of these parameters was found to exert a

Figure 2.1

Cumulative incidence of phlebitis over time in the filter and control groups

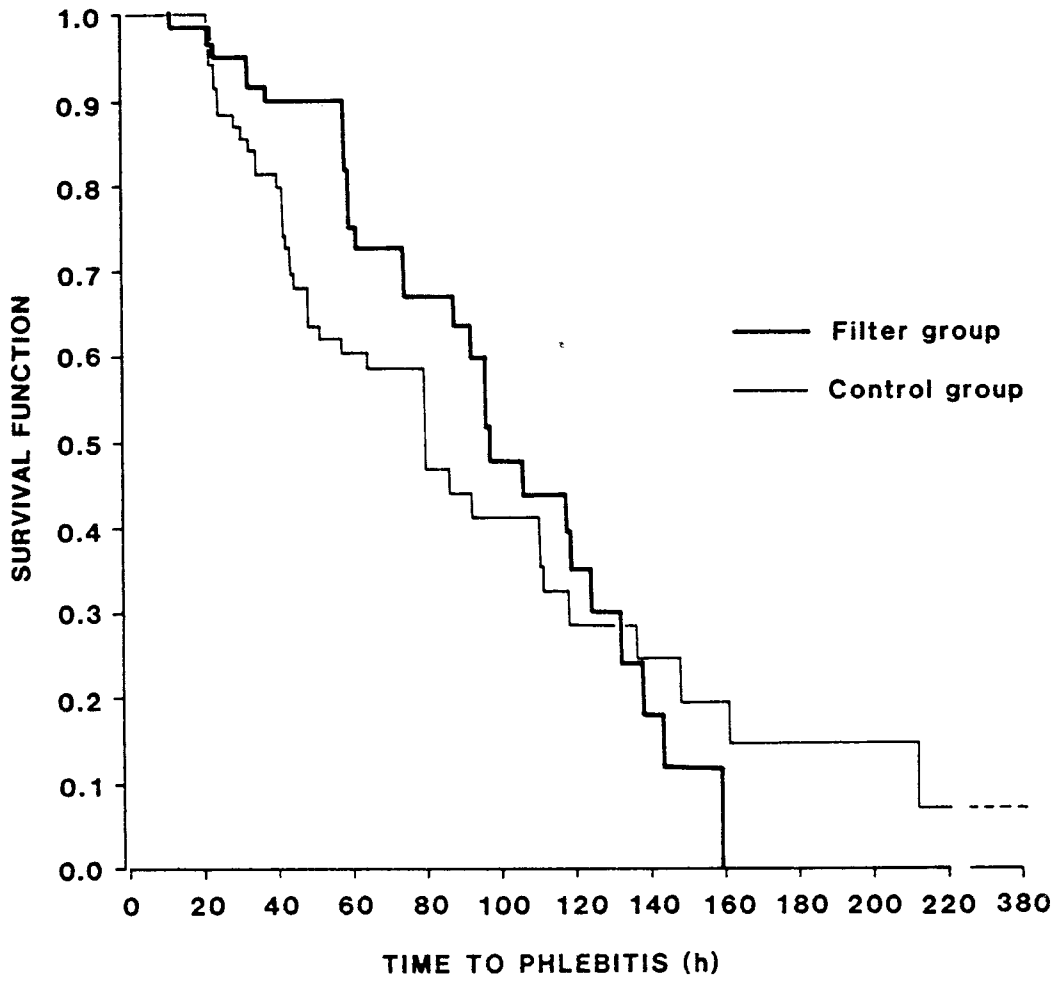


n1 = number of infusions resulting in phlebitis in the filter group

n2 = number of infusions resulting in phlebitis in the control group

Figure 2.2

Probability of not developing phlebitis, as a function of time, in the filter and control groups



statistically significant effect on the incidence of phlebitis.

Table 2.6 gives the severity of phlebitis in the filter and control groups. The difference between the filter and control groups, as regards the overall severity of phlebitis, was tested using a chi-square test with three degrees of freedom, and was not statistically significant.

The overall incidence of grade 3+ and greater phlebitis was 34% (24/70) and 18% (11/62) for the control and filter groups, respectively. This difference was statistically significant (p=0,0316) using the chi-square test. At 72 hours the incidence of grade 3+ and greater phlebitis was 24% (17/70) and 6% (4/62) in the control and filter groups, respectively. This was statistically significantly different using Fisher's two-tail exact test (p=0,0077); this test was used because, with the low numbers involved, it gives a more accurate statistic than the equivalent chi-square test.

Antibiotics were included in 90% (118/132) of infusions. The incidence of phlebitis in patients receiving intravenous antibiotics and in patients receiving the cephalosporins, cephamandole and ceftazidime, and penicillin alone is given in Table 2.7. One infusion containing antibiotics was excluded from this analysis, as high doses of heparin were administered concomitantly.

The incidence of phlebitis for infusions containing

Table 2.7

Effect of intravenous antibiotic therapy on the incidence of phlebitis.

Antibiotic therapy	Incidence of phlebitis Filter group		Control group		p*
All antibiotics	27/57	(47%)	41/61	(67%)	Ø,Ø293
Cephalosporins	7/18	(39%)	18/23	(78%)	Ø,ØlØ3
Penicillin	6/11	(55%)	1Ø/14	(71%)	> Ø,Ø5

* Differences were tested using a chi-square analysis; significance was assigned to a probability value of Ø,Ø5.

Table 2.8

Incidence of phlebitis and mean time to phlebitis with different infusion fluids

Infusion fluid	Incidence of phlebitis		Mean time to phlebitis (h)	Standard deviation
Normal Saline	52/88	(59%)	69,3	44,6
Other fluids	7/16	(43%)	48,4	31,2
Combinations*	15/28	(53%)	76,4	38,6

Note

1) * Normal saline was used in combination with other intravenous infusion fluids.

2) There were no significant differences for incidence of phlebitis or mean time to phlebitis between the three groups tested, using the chi-square test and Kruskal - Wallis one-way analysis of variance, respectively.

antibiotics was significantly greater in the control group than the filter group, at the 5% level using the chi-square test (p=Ø,Ø293). The difference was statistically significantly greater (p=Ø,ØlØ3) when the cephalosporins were tested separately, but no significant difference was found between the two groups for penicillin.

The effect of other individual intravenous medicines on the incidence of phlebitis could not be tested, as insufficient numbers were available.

Table 2.8 shows the incidence of phlebitis and mean time to phlebitis with different infusion fluids. The Kruskal-Wallis one-way analysis of variance procedure was used to compare the effect of normal saline with other intravenous infusion fluids, alone or combinations of infusion fluids, on the mean time to phlebitis. The chi-square test was used to compare the effects of infusion fluids on the incidence of phlebitis. No significant difference was found between the three groups for either parameter.

The reasons for discontinuation of intravenous infusions are given in Table 2.9. The percentages of infusions discontinued electively, and for infiltration into tissues and inadvertent removal, are approximately the same for both groups. Sixty three percent of infusions in the control group were discontinued due to phlebitis, as compared to 47% in the filter group. This difference was not statistically significant at the 5% level, using the chi-square test;

Table 2.9

Reasons for discontinuation of intravenous infusion

Reason for discontinuation	Filter group n=62		Control group n=70	
Elective	14	(22%)	13	(19%)
Phlebitis°	29	(47%)	44	(63%)
Blockage	13	(21%)	8	(11%)
Other*	6	(10%)	5	(7%)

Note

1) ° Blockage was also reported as present in 6 infusions in the filter group and 4 in the control group.

2) * This includes infiltration into tissues and inadvertent removal by patients or ward staff.

3) There was no significant difference between the two groups using chi-square analysis, as regards the reasons for discontinuation of infusions; significance was assigned to a probability value of 0,05.

however, p=0,06 and this difference may tend towards significance with a larger sample.

The percentage of infusions discontinued due to blockage was approximately twice as great in the filter group as compared to the control group, being 21% (13/62) and 11% (8/70), respectively. The difference between the filter and control groups was tested using a chi-square analysis, and was not statistically significant. Blockage was also reported as present in 6 infusions in the filter group and 4 in the control group, when phlebitis necessitated discontinuation of the infusion.

The preceeding statistical analyses showed that there were no overall statistical differences between the filter and control groups for the parameters tested, except for the incidence of phlebitis. It was therefore felt to be important to statistically evaluate the incidence of phlebitis in the control and filter groups, after elimination of any possible bias that may have been introduced by the higher incidence of blockage in the filter group.

After the exclusion of infusions discontinued due to blockage, 49 infusions remained in the filter group and 62 in the control group. Of the filter group 59% developed phlebitis, in a mean time of 77 hours, compared to 73% in the control group, in a mean time of 63 hours. The incidence of phlebitis was tested using the chi-square test and the time to phlebitis using a Kruskal-Wallis one-way

analysis of variance. No statistically significant difference was found between the two groups for either variable.

In view of the high incidence of blockage, it was deemed necessary to investigate parameters that may have influenced the development of blockage. The chi-square test was used to compare the group in which blockage occurred, with the group which was blockage free, in terms of race, cannula size, site of cannulation, sex, intravenous fluids (categorized as normal saline alone or other intravenous fluids) and smoking, whilst age was compared using the Student's t test. No statistically significant differences were found between the two groups for the parameters tested.

Summary of results

The results indicate that the filter and control groups were comparable for the parameters tested, except for the overall incidence of phlebitis. There was a statistically significant reduction in the overall incidence of phlebitis when a filter was included in-line; this was especially marked when antibiotics were included in the intravenous infusion.

This reduction in the incidence of phlebitis was not significant at the 5% level after the exclusion, from the statistical analysis, of infusions in which blockage of the access line had developed.

The overall severity of phlebitis was not statistically different when a filter was included in-line; however, the reduction in the incidence of grade 3+ and greater phlebitis in the filter group was statistically significant.

This study also demonstrated that the incidence of phlebitis increased with the duration of infusion.

Variables such as site of cannulation, size of cannula and infusion fluids used did not affect the incidence of phlebitis.

2.9 Discussion

No statistically significant differences were found between the filter and control groups, in the various variables tested, which included the incidence of phlebitis between an initial and subsequent infusion. This latter point was of particular importance to this study as many patients were used for more than one cannulation site, which reduced the variation between the groups.

The inclusion of the Ø,2 µm air venting filter in-line made a real contribution to the reduction in the incidence of phlebitis. However, the presence of the filter in-line did not affect the mean time to onset of phlebitis, the mean duration of infusion, or the overall severity of phlebitis.

The overall incidence of phlebitis in the control group

(64%) was similar to that reported by DeLuca et al. (3), Evans et al. (22), Chamberland et al.(26) and Allcutt et al. (23), all of whom used similar criteria for phlebitis.

Clinical trials suggesting the beneficial effects of in-line filters were first reported in 1973 and in all, except in the recent trial by Allcutt et al. (23), the infusions were discontinued after a specified time, ranging from 48-72 hours. In this study and that of Allcutt et al. (23), infusions were allowed to run until no longer required, or until there was a reason for removal.

In the first published clinical trial, by Ryan et al. (16), the reduction in the incidence of phlebitis between the control and filter group, from 45% to 2%, was much greater than was reported subsequently by other investigators. The great difference in the incidence of phlebitis between the control and filter groups reported by Ryan et al. (16) cannot be explained. The 45% incidence of phlebitis in their control group, after 72 hours infusion, was comparable with the 47% in this study, and the 51% in the study of Allcutt et al. (23).

Direct comparison between clinical studies is difficult, because the pore size of filters, the duration of infusion and the criteria for phlebitis varied widely between studies, as can be seen from Table 2.10.

In three studies, which demonstrated an advantage for in-line filters, infusions were allowed to run for 72 hours

Table 2.10

Clinical studies using in-line filters

Reference		Duration of study (h)	Filter size μm	Phlebitis score	Incidence of phlebitis Filter Group	Control Group
This study		a) 30	0,2	2	3/62 (5%)	10/70 (14%)
		b) 48	0,2	2	9/62 (15%)	25/70 (36%)#
		c) 72	0,2	2	15/62 (24%)	33/70 (47%)#
		d) >72	0,2	2	29/62 (47%)	45/70 (64%)#
Ryan et al.	16	72	0,45	3	1/51 (2%)	22/49 (45%)#
DeLuca et al.	3*	72	0,45	2	19/75 (25%)	44/71 (62%)#
Evans et al.	22*	72	5	2	2/24 (18%)	14/25 (56%)#
Maddox et al.	20*	48	0,22	1	4/20 (20%)	12/20 (60%)
				2	2/20 (10%)	7/20 (35%)
Rusho & Bair	18*	60	0,45	4	N S (6%)	N S (27%)#
			5	4	N S (22%)	N S (27%)
Allcutt et al.	23*	a) 72	0,2	2	32/101(31%)	47/93 (51%)#
		b) >72	0,2	2	49/101(48%)	51/93 (55%)
Collin et al.	24	NS	0,45	2	13/33 (39%)	12/27 (44%)
Swift et al.	17	72	0,45	1	7/24 (29%)	6/26 (23%)
O'Brien et al.	25	48	0,45	2	14/33 (42%)	6/15 (40%)
Chamberland et al.	26	48	0,45	1	72/107(67%)	53/84 (63%)
Thayssen et al.	27*	72	0,45	2	27/57 (47%)	33/58 (57%)
Maddox et al.	28	48	0,22	1-3	38/95 (40%)	39/100(39%)

key

* denotes a double blind-trial

# denotes a significant difference at the 5% level

N S= not stated

and similar criteria for phlebitis were applied. DeLuca et al. (3) in 1975 reported a decrease in the incidence of phlebitis, from control to filter group of 62% to 25%, Evans et al. (22) in 1976 from 56% to 10%, and Allcutt et al. (23) in 1983 from 51% to 31%.

From Table 2.10 it can be seen that after 72 hours the incidence of phlebitis in this study, when a filter was included in-line, is similar to that found by DeLuca et al. (3) and Allcutt et al. (23).

Two studies, demonstrating an advantage for filters, used shorter infusion periods. Maddox et al. (20) reported a reduction in the incidence of phlebitis, over 48 hours, from 35% to 10% when an in-line filter was included, which is comparable to the 36% and 15% of this study, over the same time period. Rusho and Bair (18) using more stringent criteria for phlebitis, equivalent to grade 3+ or greater, found no difference in the incidence of phlebitis when a 5 µm filter was included in-line; however, a reduction from 27% to 6% was obtained with a 0,45 µm filter, over approximately 60 hours. In this study the overall incidence of grade 3+ and greater phlebitis was 34% and 18% for the control and filter groups, respectively and at 72 hours, 24% and 6%.

Allcutt et al. (23) determined the survival time of intravenous infusions and found that the inclusion of a filter in-line was clinically advantageous for infusions lasting 72 hours and under, but not for infusions of over 72

hours. The incidence of phlebitis in the control and filter groups, respectively was 55% and 48% for infusions of over 72 hours. They also reported that in-line filtration prolonged the phlebitis-free survival time of infusions; only 38 (41%) infusions in the control group were able to be continued until no longer required, compared to 63 (62%) in the filter group.

In this study, the overall incidence of phlebitis was statistically significantly lower in the filter group for infusions of 25 to 130 hours duration. This difference in clinical advantage over time, when compared with the results of Allcutt et al. (23), could possibly be explained by the inclusion of antibiotics in a higher percentage of infusions in this study. This study, and those of Maki et al. (60) and O'Brien et al. (25), demonstrate that antibiotics increase the incidence of phlebitis, however, Swift et al. (17) concluded from their study that phlebitis was not associated with any particular type of additive.

Most of the studies conducted have included antibiotics and/or other additives in at least some of the infusions. However, the type of medicine infused and the number of infusions with additives cannot always be established from the published papers, except for the studies of Maddox et al. (20) and Rusho and Bair (18) in which a cephalosporin was included in all infusions.

This study, as well as those of Allcutt et al. (23), Maddox et al. (20) and Rusho and Bair (18), found the inclusion of

an in-line filter to be beneficial when antibiotics were administered through the intravenous line. This was most pronounced when the antibiotic was a cephalosporin. In comparison Chamberland et al. (26), reported that filters exerted no protective effect when irritant solutions such as cephalothin sodium or potassium chloride were infused.

A higher percentage of access lines in the filter group than the control group were discontinued in this study due to blockage. This was possibly due to an unwillingness, by ward staff, to manipulate an infusion line when a filter was included.

When infusions in which blockage of the access line occurred were excluded from the statistical analysis, there was no significant difference between the incidence of phlebitis in the filter and control groups. The possible link between blockage of the access line and the development of phlebitis is not known, therefore, it is not possible to comment on whether discontinuing the infusion due to blockage might have biased the data.

The studies showing an advantage for in-line filters reported no problems due to blockage, but the pore size of the filters was larger than Ø,2 µm, except in the studies of Maddox et al. (2Ø) and Allcutt et al. (23).

In five of the studies showing no clinical advantage for in-line filters (17,24,25,26,27), a Ø,45 µm filter was used. In the study by Collin et al. (24), filters were changed at

48-hour intervals or when the filter blocked, which occurred with 53% of the filters. Chamberland et al. (26) and Thayssen et al. (27) experienced problems with blockages. Chamberland et al. (26) replaced filters every 24 hours or sooner if blockage occurred and they state that it was not possible to conduct a double-blind study as the placebo filter would not become blocked.

Previous studies utilised filters which were unable to release air entering the filter, and this caused blockage. The filters used in this study and those of Allcutt et al. (23) and Maddox et al. (28) contained a hydrophobic membrane, which eliminated air, as well as a large hydrophilic membrane for filtration of fluids, which allowed flow rates to be maintained.

The published studies, except for the study by Rusho and Bair (18) and part of the study by DeLuca et al. (3), do not appear to have complied with present requirements that filters should be changed at daily intervals, to prevent the possibility of micro-organisms retained on the filter from liberating endotoxins (107). This procedure itself could increase the risk of microbial contamination.

DeLuca et al. (3) found the incidence of phlebitis to be 32%, when the filter and administration set were changed daily, as opposed to 12% when the filter was not changed over the 72 hours of the study. This difference could be due to trauma caused at the cannulation site when the filter and infusion set were changed, or to microbial

contamination. Rusho and Bair (18) did not investigate the effects of filter changes on the incidence of phlebitis.

The incidence of phlebitis increased with time, for both the control and filter groups. This is in agreement with the study of Thayssen et al. (27), who stated that the cumulative risk of developing post-infusion phlebitis increased with the duration of infusion. They found that after 72 hours of infusion more than 80% of patients developed phlebitis.

CHAPTER 3

MICROBIOLOGICAL STUDIES

3.1 Aim

This section of the investigation included evaluation of microbial contamination of in-line filters, skin at the site of insertion of the cannula, and cannulae. The data collected were used to determine:

a) if there is any correlation between the number of additives to the infusion system and microbial contamination of in-use filters

b) if filters reduce microbial contamination of the cannula tips, and

c) if there is any correlation between microbial contamination of the skin, or the cannula tip, and phlebitis.

3.2 Location

Microbiological evaluation of filters, swabs and cannulae was carried out in the laboratories of the Department of Medical Microbiology at Groote Schuur Hospital.

3.3 Materials and methods

3.3.1 Sampling of filters

Filters were replaced in the patient's access line daily, to

prevent the accumulation and proliferation, on the filter, of Gram-negative endotoxin-producing bacteria (107).

The patient's skin surrounding the filter was cleansed with 70% ethyl alcohol. The intravenous infusion was interrupted, using the clamp on the administration set, the used filter was disconnected and the filter inlet plugged with a sterile stopper. A new filter was attached to the access line, primed, and then connected to the cannula, in place of the used filter. The outlet of the used filter was plugged with a sterile stopper and labelled with the patient's name, trial number, date and time of removal.

In the Department of Medical Microbiology the filters were washed with 50 ml of sterile normal saline, in an attempt to remove any residual inhibitory drug, and opened using a 50 ml bolus of sterile air under pressure. The air was previously sterilized using a sterile Millex® FG 0,2 µm filter (Batch No CIA 89203).

The filter membranes were removed aseptically from the filter casing, using a flamed and cooled scalpel, and treated as follows:

i) The central membrane was cultured:

   a) aerobically by placing the container side of the membrane onto the surface of a 2% blood agar plate, and allowing it to remain in contact with the surface for one minute prior to removal.

   b) anaerobically by placing it in cooked meat medium.

ii) The container side of the two outer membranes was placed on 2% blood agar and allowed to remain in contact with the surface for one minute prior to removal. These membranes were not placed in cooked meat medium due to the possibility of contamination of the patient side of the membranes via the air venting apertures.

After incubation at 37°C for 48 hours, micro-organisms from the blood agar plates and cooked meat medium were identified. The blood agar plates were incubated for a further 72 hours at 37°C and any fungal growth identified.

3.3.2 Controls

Positive and negative controls were prepared using 0,2 µm filters.

Candida albicans and β-haemolytic streptococci were used to prepare positive controls.

Sterile normal saline was inoculated with Candida albicans, and then two 50 ml aliquots were drawn into 50 ml sterile syringes and passed through two 0,2 µm filters.

This was repeated for β-haemolytic streptococci.

Negative controls were prepared similarly using sterile normal saline.

The filters acting as positive and negative controls were

then processed in the same way as filters obtained from patients.

3.3.3 Sampling of skin and cannula tips

The skin was sampled for microbial contamination, at the site of insertion of the cannula, immediately before removal of the cannula.

Swab 1 was taken from the site of insertion of the cannula, prior to cleansing of the skin, using a sterile Transwab® MW 170 (Batch Number 01 1021) moistened with Amies clear transport medium (108,109). The swab was then inserted into Amies medium in the Transtube.

The skin surrounding the site of cannulation was then cleansed, using a centrifugal motion, with 70% ethyl alcohol and allowed to dry.

Swab 2 was taken, in a similar manner to swab 1, after the skin had been cleansed.

The cannula was then withdrawn from the patient's vein with sterile forceps, and the distal 2 cm cut off with sterile scissors and placed in the transport medium in a sterile Transtube.

The swabs and cannula tips were transferred aseptically into cooked meat medium, incubated for 48 hours at 37°C, and the cultured organisms identified.

3.4 Statistical analysis

The effect of skin contamination on mean time to phlebitis was investigated using the Kruskal-Wallis one-way analysis of variance (105). For all other statistical analyses either the chi-square test or Fisher's two-tail exact test were used (104).

The null hypothesis was that there is no statistically significant difference in the parameters tested between the two groups under investigation. Significance was assigned to a probability value of less than 0,05; where an association is reported as not significant, this means a probability value of greater than 0,05.

3.5 Results

Microbiological results for each patient are given in Appendix II. Where reference is made to Trial Numbers, the first three digits indicate the patient number, and the digit following the oblique indicates the Trial cannulation site number.

Microbiological results were obtained for 209/216 filters from 62 infusions. Four filters were inadvertently discarded by ward staff or patients, and 3 could not be opened without contaminating the filter membranes.

Cannula tips and swabs from 112/132 intravenous infusions, 55 from the control group and 57 from the filter group, were

examined for microbial contamination. Twenty infusions were discontinued by ward staff or patients and, therefore, swabs and cannulae could not be collected.

3.5.1 Filters

The negative controls were all culture negative and the positive controls were all culture positive for the seeded organisms.

Contaminated filters originated from 19/62 (31%) of infusion systems with filters in-line.

From Table 3.1 it would appear that contamination of the infusion system was not affected by the number of intravenous medicines added. A chi-square analysis was performed using three categories, Ø, 1 and 2 or more additives; no significant relationship was found between the number of additives and microbial contamination of in-use filters from infusion systems.

Twenty eight of the 2Ø9 filters cultured (13%) were contaminated. Fifteen of the contaminated filters originated from 6 infusions and the remaining 13 originated from one infusion each. From Table 3.2 it would appear that there was no apparent association between the number of filters used per infusion, which reflects the number of days of infusion, and the presence of microbial contaminants. An analysis of the patient data in Appendix II indicates that there was no discernible pattern in the day to day sequence

Table 3.1

Relationship between the number of intravenous (IV) additives and contamination of filters in infusion systems

Number of IV additives per infusion system	Number of infusion systems	Infusion systems with contaminated filters	
		Number	%
Ø	4	4	1ØØ
1	32	8	25
2	16	5	31
3	8	1	13
4	1	1	1ØØ
5	Ø	-	-
6	Ø	-	-
7	1	Ø	Ø

Table 3.2

The incidence of contaminated filters obtained from infusions

Number of filters/ infusion	Number of infusions	Infusions with contaminated filters		Contaminated filters from each infusion				
		Number	%	Ø	1	2	3	4
1	7	1/7	14	6	1	Ø	Ø	Ø
2	13	4/13	31	9	4	Ø	Ø	Ø
3	17	5/17	3Ø	12	4	1	Ø	Ø
4	8	3/8	38	5	Ø	2	Ø	1
5	6	2/6	33	4	1	1	Ø	Ø
6	8	4/8	5Ø	4	3	Ø	1	Ø
7	2	Ø/2	Ø	2	Ø	Ø	Ø	Ø
8	1	Ø/1	Ø	1	Ø	Ø	Ø	Ø

of contaminated filters.

Table 3.3 summarizes the organisms isolated from filters. Staphylococcus epidermidis was the most common micro-organism isolated from filters, accounting for 69% of all isolates. Two species of fungi, Aspergillus nidulans and a Cephalosporium species, were isolated from the same filter.

A single species of bacterium was isolated from 21 filters and two species from 6 filters.

3.5.2 Skin

Microbiological results for skin contamination, at the site of insertion of the cannula prior to removal of the cannula, were obtained for 112 infusions.

i) Microbial contamination of the skin prior to cleansing with 70% ethyl alcohol.

Fifty seven of the 112 (51%) skin swabs taken prior to cleansing of the skin at the cannulation site (swab 1) yielded the micro-organisms listed in Table 3.4. Staphylococcus epidermidis was the most commonly cultured micro-organism; Bacillus, Corynebacterium, Enterococcus and Micrococcus species were isolated more than once.

Forty nine swabs were culture-positive for a single

Table 3.3

Micro-organisms cultured from in-use filters

Micro-organism	Number of isolates	Filters with multiple isolates
Aspergillus nidulans	1	1
Bacillus sp	4	1
Cephalosporium sp	1	1
Proteus sp	1	1
Staphylococcus aureus	1	1
Staphylococcus epidermidis	24	6
β-haemolytic streptococcus	1	1
Non-haemolytic streptococcus	2	2

Table 3.4

Micro-organisms cultured from the skin, at the site of insertion of the cannula, prior to cleansing

Micro-organism	Number of isolates	Swabs with multiple isolates
Bacillus sp	7	3
Bacillus rotans	2	1
Corynebacterium sp	2	1
Enterococcus sp	4	3
Micrococcus sp	3	2
Staphylococcus aureus	1	1
Staphylococcus epidermidis	47	6
Non-haemolytic streptococcus	1	1

species of organism, 6 for two species and 2 for three species.

Table 3.5 gives the incidence of skin contamination prior to cleansing of the skin and removal of the cannula. In the filter group 44% of infusions were associated with skin contamination at the site of insertion of the cannula, compared with 58% in the control group. No statistically significant difference was found, using a chi-square test, between the filter and control groups.

From an analysis of the patient data in Appendix II it was found that in 9 of the 19 infusions with contaminated in-line filters, the same contaminants were cultured from the filters and the skin prior to cleansing.

ii) Microbial contamination of the skin after cleansing with 70% ethyl alcohol.

Fifteen of the 112 (13%) skin swabs, taken after cleansing of the cannulation site with 70% ethyl alcohol (swab 2), were contaminated with the micro-organisms detailed in Table 3.6. Staphylococcus epidermidis was the most common contaminant; Staphylococcus aureus and Bacillus, Enterococcus, Micrococcus and Penicillium species were also isolated.

A single species of micro-organism was isolated from 11

Table 3.5

Incidence of skin contamination with micro-organisms, at the site of insertion of the cannula, prior to cleansing

Skin contamination	Filter Group n=57	Control Group n=55
Present	25 (44%)	32 (58%)
Absent	32 (56%)	23 (42%)

There was no statistically significant difference between the filter and control groups using a chi-square test.

Table 3.6

Micro-organisms cultured from the skin, at the site of insertion of the cannula, after cleansing

Micro-organism	Number of isolates	Swabs with multiple isolates
Bacillus sp	2	1
Enterococcus sp	4	3
Micrococcus sp	1	Ø
Penicillium sp	1	Ø
Staphylococcus aureus	2	1
Staphylococcus epidermidis	9	2

swabs and two species from 4 swabs.

Twelve of 57 postcleansing swabs from the filter group, and 3/55 from the control group were contaminated. This difference was significant at the 5% level, using Fisher's exact test (p=Ø,Ø242).

One infusion, Trial Number Ø33/1, was associated with a culture-positive postcleansing swab, but a culture-negative precleansing swab, and in 4 infusions, Trial Numbers Ø23/1, Ø27/1, Ø66/1 and Ø68/1, the organisms on the two swabs differed.

The incidence of phlebitis following infusion was approximately the same whether or not micro-organisms were isolated from the skin. Phlebitis developed in a mean time of 64 hours, in 61% (35/57) of the group with skin contamination, and 74 hours in 55% (3Ø/35) of the group with no skin contamination at the site of insertion of the cannula.

A chi-square analysis confirmed that microbial contamination of the skin had no significant effect on the incidence of phlebitis. Using the Kruskal-Wallis one-way analysis of variance, skin contamination was found to have no significant effect on the mean time to phlebitis. This nonparametric method of analysis was used to compare cases with or without skin contamination, since the time to phlebitis did not have a normal distribution.

3.5.3 Cannula tips

Twelve of the 112 (10,7%) cannula tips cultured were contaminated with the organisms listed in Table 3.7. The micro-organism most frequently isolated was Staphylococcus epidermidis; four cannula tips were contaminated with 2 species of micro-organism, and eight with a single species. There was no instance of septicaemia associated with a contaminated cannula.

Micro-organisms were isolated from 8/57 (14%) cannula tips in the filter group, compared to 4/55 (7%) in the control group. This difference was not statistically significant using Fisher's exact test.

The incidence of phlebitis was 67% (8/12) when cannula tip contamination was present and 57% (57/100) when contamination was absent, see Table 3.8. The mean time to phlebitis was 70 hours and 68 hours, respectively. Fisher's exact test was used to compare the incidence of phlebitis, and the Kruskal-Wallis one-way analysis of variance was used to compare mean time to phlebitis, in the presence and the absence of cannula tip contamination; no statistically significant differences were found.

The mean duration of cannulation for the 12 contaminated cannula tips was 78 hours as compared to 81 hours for the uncontaminated cannula tips. The Kruskal-Wallis one-way analysis of variance confirmed that microbial contamination of cannula tips had no significant effect on the mean

Table 3.7

Micro-organisms isolated from cannula tips

Micro-organism	Number of isolates	Cannula tips with multiple isolates
Bacillus sp	2	1
Enterobacter sp	1	1
Enterococcus sp	2	2
Micrococcus lutea	1	1
Staphylococcus aureus	1	1
Staphylococcus epidermidis	9	2

Table 3.8

Correlation between incidence of cannula tip contamination and phlebitis

Phlebitis	Contaminated cannula tips n=12	Uncontaminated cannula tips n=100
Present	8 (67%)	57 (57%)
Absent	4 (33%)	43 (43%)

There was no statistically significant difference in the incidence of phlebitis, using the Fisher's exact probability test.

duration of infusion.

Antibiotics were included in 7/12 (58%) of infusions in which cannula tip contamination was present, and in 93/100 (93%) of infusions in which cannula tip contamination was absent. This difference was statistically significant using the Fisher's exact test (p=0,003).

From Table 3.9 it can be seen that the same species of micro-organisms were isolated from the skin, prior to cleansing, and the cannula tips in 7/12 infusions. Filters were included in-line in 8/12 infusions with contaminated cannula tips (Table 3.9). In four of these 8 infusions, filters and cannula tips were contaminated; in 3 instances the same species of micro-organism, Staphylococcus epidermidis, was isolated from both the filters and cannula tips.

Summary of results

In this study there was no correlation between microbial contamination of the skin or cannula tips, and the occurrence of phlebitis or mean time to phlebitis.

In addition, there were no significant differences between the filter and control groups, as regards contamination of the skin prior to cleansing or of the cannula tips. This indicates that skin and cannula tip contamination were not significant variables in the development of phlebitis and that in-line filters did not reduce the microbial

Table 3.9

Correlation between microbial contamination of swabs, cannula tips and filters, phlebitis and duration of cannulation

Trial Number	Number contam. filters	Micro-organisms isolated Swab 1	Swab 2	Cannula	Phlebitis score	Antibiotic included in infusion	Duration of cann. (d)
Ø11/2	1/2*	H	-	H	2+	N	2,4
Ø19/1	Ø/6	-	-	A+C	3+	Y	5,8
Ø2Ø	2/3*	H	H	H	2+	N	2,9
Ø26/1	Control	B+D+G	D+G	D+G	Ø	N	3
/2	2/4*	D	-	E+H	1+	N	3,1
Ø35/1	Ø/4	-	-	H	2+	Y	3,5
/2	Control	-	-	H	1+	Y	2,5
Ø46/3	1/2	H	H	H	1+	N	1,8
Ø5Ø	Control	H	-	H	3+	Y	4,8
Ø53	Ø/1	A	A	A	3+	Y	1,5
Ø71/2	Ø/6	-	-	D+H	3+	Y	5,7
Ø72/1	Control	F+H	-	H	2+	Y	1,8

key

* infusions in which the same mico-organisms were isolated from both the filters and cannula tips.

contam.	contamination
cann.	cannulation
Y	yes
N	no
A	*Bacillus* sp
B	*Corynebacterium* sp
C	*Enterobacter* sp
D	*Enterococcus* sp
E	*Micrococcus lutea*
F	*Micrococcus* sp
G	*Staphylococcus aureus*
H	*Staphylococcus epidermidis*

Note: The criteria for phlebitis are given on page 37

contamination of cannula tips. The fact that the incidence of skin contamination, after cleansing the skin, was significantly greater in the filter group appears to be of little clinical importance.

Contaminated filters were obtained from 19/62 infusions. In three infusions, the same species of micro-organism was isolated from the filters and cannula tips, which may indicate retrograde contamination of the filters from the cannulae. Infusions running for prolonged periods, with a consequent increase in the number of filter changes, did not demonstrate a greater incidence of contamination than infusions running for shorter periods. In addition, contamination of infusion systems was not increased by an increment in the number of intravenous medicines added.

There was a low level of cannula tip contamination, which could possibly be explained by the high percentage of antibiotics administered.

There was a significant reduction in the incidence of microbial contamination between the precleansing (51%) and postcleaning (13%) skin swabs, thus proving the efficacy of 70% ethyl alcohol as a skin disinfectant.

The principal micro-organism isolated from filters, swabs and cannula tips was Staphylococcus epidermidis; other common skin commensals such as Bacillus, Enterococcus, Micrococcus and Corynebacterium species were also isolated.

3.6 Discussion

3.6.1 Contamination of cannula tips

The incidence of cannula tip contamination in this study, 10,7%, falls within the wide reported range of 3,8% to 57% (32).

This study, like those of Fuchs (38), Cheney and Lincoln (34) and Band and Maki (37) demonstrated a low level of cannula contamination, even though the technique used was culture in broth and not the semiquantitative method recommended by Maki et al. (39).

Maki et al. (39) claimed that the clinical interpretation of a positive broth culture was unclear, as a positive culture may result from very few organisms. This may account for the relatively poor reported correlation between phlebitis and cannula tip microbial contamination (32,41). They suggested that the semiquantitative method, utilising a plate culture, differentiates infection from contamination. In their study, 10% of cannula tips yielded significant growth on a plate culture and this was interpreted as contamination.

In this study, using the broth culture technique, 12/112 (10,7%) of cannula tips were culture-positive and 67% (8/12) of contaminated cannulae were associated with phlebitis. These figures are similar to the 10% (25/250) and 64% (16/25) respectively, reported by Maki et al. (39).

However, contrary to the findings of Maki et al., there was no significant difference between the number of culture-positive and culture-negative cannula tips associated with phlebitis.

In this study the majority of cases of phlebitis were not associated with culture-positive cannula tips and, in fact, most studies have failed to demonstrate a relationship between phlebitis and a positive cannula tip culture (24,34,35,36,37,38,40,110).

In contrast to the reports of Druskin and Siegel (35), Collins et al. (40) and Maki (5), there was no association in this study between duration of cannulation and culture-positive cannula tips.

The inclusion of a filter in-line did not reduce the incidence of cannula tip contamination. This is in agreement with Collin et al. (24); however, their cannula tip contamination rate, 58%, was much higher.

Maki (30,31) stated that cannula related infections derived mainly from the patients own skin flora or from personnel inserting or handling the cannula. The most common isolates reported are Staphylococcus aureus, Staphylococcus epidermidis, Gram-negative bacilli, Enterococci and Candida (8,13,31,32,33,110). In this study similar contaminants were isolated, except for Candida.

Maki et al. (32) pointed out that phlebitis may dispose to

an increased risk of cannula-related sepsis and that, whilst phlebitis is usually a physicochemical phenomenon, in its later stages secondary infection may occur and lead to sepsis. In this study no case of sepsis was associated with a contaminated cannula, but, if the sepsis rate of Ø,5% as reported by Rhame et al. (41) is considered, there were insufficient numbers to demonstrate this association.

3.6.2 Contamination of filters

Contamination of in-line filters has been reported in the range of 2,8 to 27% (19,24,55,61,63).

In this study, in which the infusion line was broken daily to change filters, contaminated filters originated from 19 of 62 (31%) infusions, and 13% (28/2Ø9) of the filters cultured were contaminated. This is similar to the 11% (7/65) contamination rate for filters reported by Rusmin et al. (63), but lower than the 21% and 27% reported by Collin et al. (24) and Newman et al. (61), respectively. In these studies (24,61,63) filters remained in-line for the duration of the infusion, unless blockage occurred, and the incidence of contamination of filters reflects the incidence of contamination for the infusion system.

Newman et al. (61) stated that the main source of contaminating microbes seemed to be the hands of personnel changing infusion containers, as Staphylococcus epidermidis was the most common contaminant. The common skin commensals were isolated from filters in this study, which does imply

that the main source of contamination was the personnel involved in the preparation and administration of intravenous infusions and medicines, rather than the manufacturing process.

3.6.3 Contamination of infusion systems

If contamination of filters reflects contamination of intravenous solutions, or additives, or administration sets, or contamination during use, rather than contamination due to daily filter changes or retrograde contamination from the cannula, it follows that 31% of infusion systems were contaminated in this study.

This percentage of contamination is similar to the 27% reported by Newman et al. (61) but is considerably higher than the 11% reported by both Maki et al. (60) and Rusmin et al. (63), which could possibly be explained by the daily breaking of the infusion line when changing filters. In the study by Maki et al. (60) infusion fluid from 10/94 (11%) in-use systems contained micro-organisms, usually staphylococci or bacilli. Contamination appeared to be related to the duration of continuous intravenous therapy as 9/61 systems in-use for longer than 48 hours were contaminated, compared to 1/33 of those in-use for less than 48 hours. The occurrence of phlebitis in 29/94 (32%) of cases did not correlate with contamination of the infusion system.

The incidence of in-use contamination of intravenous

infusions has been associated with increased duration of uninterrupted infusion (2,49,54), but in this study there appeared to be no correlation between the duration of infusion and contamination of the infusion system.

This study, in agreement with those of Letcher et al. (54), Hughes (57) and Hanson and Shelley (59), demonstrated little correlation between the addition of intravenous medicines and the contamination rate of intravenous infusions. In contrast, studies conducted by D'Arcy and Woodside (56) and Woodside et al. (62) indicate that drug additives may be a causative factor in the in-use contamination of infusion fluids.

CHAPTER 4

PARTICLE SIZE ANALYSIS

4.1 Aim

This study was undertaken in order to determine:

a) the particulate load of intravenous infusion fluids, and medicines entering the patient's systemic circulation

b) if the particle counts of the infusion fluids and medicines comply with the British Pharmacopoeia 1980 specifications (101)

c) if an in-line filter reduces the particle count of infusion fluids and medicines.

4.2 B P 1980 Limit test for particulate matter

According to the B P 1980 (101) specifications the average count for the undiluted infusion fluid, using an apparatus which operates on the electrical zone-sensing principle, eg the Coulter Counter, must not exceed 1000 particles/ml greater than 2 μm, and 100 particles/ml greater than 5 μm.

At present, this test is only applicable when the volume of intravenous infusion fluid is 100 ml or more and is specified in the particular monograph; the test does not apply to small volume parenteral injections or to powders requiring reconstitution prior to injection.

4.3 Location

Particle counts were carried out in the Department of Pharmacology, Medical School, University of Cape Town.

4.4 Materials and methods

Particle counts were performed using a Coulter Counter®, Model ZM , fitted with a 70 µm orifice tube. The Coulter Counter detects, counts, and measures the size of individual particles by changes in electrical resistance that occur when particles pass singly through a small orifice. The instrument measures particle volume, and the diameter of a particle is expressed as the diameter of a sphere, with the same volume as the particle. The results are obtained as numbers of particles equal to or larger than a specified size.

The Coulter Counter was calibrated with a dispersion of latex spheres, of diameter 4,77 µm, in sterile normal saline filtered through a 0,2 µm air venting filter, using the half count technique (111). Particle counts were performed on intravenous infusion electrolyte solutions and on intravenous medicines to establish the number of particles of size 2 µm and greater, 5 µm and greater and 10 µm and greater. Sterile normal saline filtered through a 0,2 µm air-venting filter was used both as the diluent and as the electrolyte solution when preparing intravenous medicines for particle counting.

A minimum of two samples of each product was counted, each count being performed six times, and the mean value taken. Samples of 0,05 ml were counted; therefore, the mean value was multiplied by 20 to give the number of particles/ml.

Prior to sampling, each container was inverted 20 times to suspend particles uniformly. Samples were transferred to a particle-free cuvette (washed with filtered sterile normal saline) and placed in an ultrasonic bath for 30 seconds prior to counting, in order to disperse aggregates of particles and minimize air bubbles.

Special precautions were NOT taken to avoid the introduction of extraneous particulate matter during the preparation of medicines and all particle counts were made at room temperature, in order to approximate clinical conditions.

4.4.1 Preparation of samples

i) Intravenous infusion fluids

Intravenous infusion fluids were transferred from the infusion container, via a Continu-Flo Solution Administration Set (Batch No 111 S 513) into a cuvette and counted.

The counts were repeated following filtration of the infusion fluids through a 0,2 µm air venting filter.

ii) Intravenous medicines

Intravenous medicines in solution were added to a 50 ml minibag of sterile normal saline (Baxter Batch No 203V141) via a sterile 10 ml Promex syringe (Batch No 2/119). Powdered intravenous medicines, requiring reconstitution prior to administration, were prepared by adding water for injection (see Table 4.3), via a sterile 10 ml Promex syringe. When the powder was dissolved, the resulting solution was transferred via the syringe to a 50 ml minibag of normal saline, as is done in the wards. Fifteen minutes after preparation the mixed solution was transferred via an Add-A-Line (Batch No 111 S 533) into a cuvette and counted.

The counts were repeated, following filtration of the prepared medicines through a 0,2 µm air venting filter.

A particle size analysis was performed on the following medicines for intravenous administration both before and after filtration through an 0,2 µm air venting filter.

Intravenous medicine	Proprietary name	Batch No
Amikacin	AMIKIN®	15M0002M2
Ampicillin	PENBRITIN®	44287
Benzylpenicillin	CRYSTAPEN®	1AP672F
Cefamandole	MANDOKEF®	A462U3209180
Ceftazidime	—	GCR2308/A/3
Cloxacillin	ORBENIN®	44681
Chloramphenicol	CHLOROMYCETIN®	009417
Co-trimoxazole	SEPTRAN®	675J
Erythromycin	ERYTHROCIN®	33862MY
Fusidic acid	FUCIDIN®	PODA 1/84
Gentamicin	FERMENTMYCIN®	42444
Rolitetracycline	REVERIN®	060W
Tobramycin	NEBCIN®	A809U

4.5 Results

The particulate content of intravenous infusion fluids and medicines is given in Tables 4.1, 4.2 and 4.3.

The results of the particle size analysis show little correlation between samples from the same batch. All three minibags of normal saline, but only two of the ten samples of intravenous infusion fluids, complied with the B P 1980 limit test for particulate matter, prior to filtration. All of the intravenous medicines failed to comply with the limit test.

Particle counts for the majority of samples of powders to be reconstituted prior to use were greater than for intravenous medicines supplied in solution.

Filtration of intravenous infusion fluids and medicines, through the 0,2 µm air venting filter, brought all samples to within the B P limits for particulate matter, except for one sample of normal saline (Labethica Batch No 778LI) at the 2 µm level and one sample of normal saline (Baxter Batch No 202v11) at the 5 µm level, and one sample of ampicillin.

Summary of results

Infusion fluids as supplied by the manufacturer's are expected to comply with the limit test for particulate matter specified in the 1980 B P. This study demonstrates that the majority of the intravenous fluids sampled, after

Table 4.1

Particle size analysis of intravenous infusion fluids after passage through an administration set

Sample	Sample Number	Mean particle count/ml Unfiltered solution ≥2 µm	≥5 µm	≥10 µm	Filtered solution ≥2 µm	≥5 µm	≥10 µm
Normal Saline	1	4673	173	Ø	70	Ø	-
Baxter 200 ml	2	1643	46	Ø	83	Ø	-
Batch No 202V11	3	2256	90	Ø	220	143	-
	4	896	50	Ø	223	45	-
Normal Saline	1	2510	226	Ø	1033	43	-
Labethical1000 ml	2	650	66	Ø	300	Ø	-
Batch No 7748LI	3	1023	43	Ø	-	-	-
Dextrose 5% in	1	1423	206	Ø	210	20	-
Normal Saline	2	3026	53	Ø	143	Ø	-
Baxter 200 ml	3	2216	60	Ø	403	10	-
Batch No 111V670							

TABLE 4.2

Particle size analysis of 50 ml minibags of normal saline, and intravenous medicines in solution, in 50 ml minibags of normal saline after passage through an Add-A-Line

Medicine	Sample Number	Mean particle count/ml Unfiltered solution ≥2 µm	≥5 µm	≥10 µm	Filtered solution ≥2 µm	≥5 µm	≥10 µm
Normal saline	1	563	60	0	63	0	-
50 ml minibag	2	300	56	0	40	0	-
	3	456	30	0	56	0	-
Amikacin	1	3790	222	0	113	0	0
500 mg/2 ml	2	12546	1296	180	-	-	-
	3	9466	446	0	-	-	-
Co-trimoxazole	1	2926	125	0	-	-	-
480 mg/5ml	2	5426	346	0	-	-	-
	3	2566	230	0	-	-	-
Gentamicin	1	2276	140	0	20	0	0
80 mg/2 ml	2	2766	153	0	20	0	0
	3	1993	56	0	10	0	0
Tobramycin	1	1696	80	0	-	-	-
40 mg/2 ml	2	1293	160	0	-	-	-
	3	3460	180	0	-	-	-

TABLE 4.3

Particle size analysis of reconstituted powders for intravenous administration, in 50 ml minibags of normal saline after passage through an Add-A-Line

Medicine	Sample Number	Mean particle count/ml Unfiltered solution ≥2 µm	≥5 µm	≥10 µm	Filtered solution ≥2 µm	≥5 µm	≥10 µm
Ampicillin	1	10446	203	-	1900	126	-
500 mg+3ml WI	2	4950	226	-	153	10	-
	3	13673	306	-	446	40	-
Benzylpenicillin	1	2533	116	-	106	0	-
sodium 600 mg	2	6010	193	-	70	0	-
+3ml WI	3	4843	206	-	-	-	-
Cefamandole 1g	1	18170	1416	113	220	20	-
+5ml WI	2	6486	440	0	50	0	-
Ceftazidime 1g	1	3920	233	0	46	0	-
+3ml WI	2	9146	306	0	76	0	-
Cloxacillin	1	7083	346	0	160	0	-
500 mg+3ml WI	2	18833	2140	0	193	20	-
	3	5143	393	0	32	0	-
Chloramphenicol	1	41333	1516	103	73	0	-
1 g+7,5ml WI	2	51473	1056	53	643	0	-
	3	46706	966	16	40	0	-
Diethanolamine	1	47736	3660	316	213	36	-
fusidate 500mg	2	70956	5050	570	376	33	-
+50ml buffer*	3	39503	2806	176	560	30	-
Erythromycin	1	9716	486	0	560	63	-
300 mg+6ml WI	2	6436	343	0	86	0	-
	3	7960	380	0	133	13	-
Rolitetracycline	1	5333	500	0	153	0	-
275 mg+10ml WI	2	6356	333	0	550	0	-
	3	14576	936	0	666	0	-

WI = water for injection

* sterile phosphate buffer solution was supplied with the powder

passage through administration apparatus, did not comply with the B P limit test.

Particle counts for intravenous medicines in 50 ml minibags of normal saline all failed to comply with the B P limit test for particulate matter.

Filtration of infusion fluids and medicines reduced the particle counts to within B P specifications in the majority of samples tested.

4.6 Discussion

Myers (55) stated in 1972, that infusion bottles and giving sets are a source of particles and that micro-organisms can enter intravenous fluids. Logically, claims Myers, there should be a sterile bacteriological filter at the point where fluids enter the vein, so that micro-organisms and any particles from the rubber bung, glass bottle or plastic container, solution, giving set and tubing would be filtered out.

Since then there has been an increase in the number of medicines administered intravenously and the particulate load of intravenous medicines is high, especially for powders requiring reconstitution. These microcrystalline drug particles, polymeric substances or degradation products, which are present in the subvisible range (96) and administered during intravenous therapy, may react with tissue proteins and thereby cause or contribute to the

complications of phlebitis.

Traces of macromolecular proteins of peptide complexes possessing allergenic properties have been reported in the cephalosporins and penicillins (87,112), which were supposedly pure by pharmaceutical standards. In addition to the protein contaminants, polymers are formed in the beta lactam antibiotics either through internal rearrangement or degradation. These polymers may conjugate with tissue proteins after injection and may be involved in delayed allergic reactions.

The presence of particulate matter in antibiotic preparations supplied as powders has been demonstrated in the past (95), but little information is available on the more recently introduced intravenous medicines.

Rebagay et al. (96) commented that the medication added during intravenous fluid administration often contained more particles than the large volume parenteral itself. This was also found by Mehrkens et al. (68) and in this study.

The considerable variation between particle counts for intravenous products within a batch could be partially explained by differences in the number of particles released by the administration sets or syringes. Studies are required, however, to determine the extent of inter-batch variation as well as the variation between manufacturers' products. Studies are also required to identify the particulate matter and determine its origin.

CHAPTER 5

SUMMARY and CONCLUSION

This study demonstrates that the incidence of phlebitis is significantly reduced by the inclusion of a Ø,2 µm air venting filter in-line. The efficacy of the filter in reducing phlebitis was most pronounced when intravenous antimicrobial agents, especially the cephalosporins, were administered.

The inclusion of an in-line filter did not reduce the incidence of cannula tip contamination and a relationship was not found between phlebitis and microbial contamination of cannula tips or skin at the site of insertion of the cannula.

The incidence of microbial contamination of infusion systems was high, 31%, as determined from the number of infusion systems with contaminated filters. A relationship could not be established, however, between microbial contamination of infusion systems, and the number of filters included, or the number of intravenous additives to the infusion system.

Intravenous additives, and in particular the powders requiring reconstitution prior to administration, were heavily contaminated with particles and would not pass the B P limit test for particulate matter in large volume parenteral products. After filtration, particle counts of the majority of samples tested complied with the B P limit

test.

It may be postulated that the reduction in the incidence of phlebitis was a result of the removal of particulate matter rather than the removal of micro-organisms from the intravenous system.

The major deficiencies in this study were:

a) the lack of data on microbial contamination of infusion systems in the control group. This made it impossible to establish whether the daily filter change affected the incidence of contamination of infusion systems;

b) the fact that very few patients received a single medicine for therapy. This made it impossible to establish a relationship between the particulate load of additives and phlebitis;

c) the large number of variables between patients. This was overcome partially by using patients for more than one infusion period, which resulted in the filter and control groups being comparable as regards the parameters tested; and

d) that some cases of phlebitis may have been missed as many patients were discharged immediately after the intravenous infusion was discontinued with the result that the intravenous sites could not be inspected the day after removal of the cannulae.

This study, in contrast to six of the twelve published clinical reports, confirmed the clinical advantage of including a filter in-line. The other six papers reported on the clinical advantage of using in-line filters. One of these six studies (20) failed to show a significant decrease in the incidence of phlebitis in the filter group, when the criteria used in this study are applied; one (18) failed to report on the number of patients in the control and filter groups; and one was not blinded (16). In another study (22) a 5 µm pore size filter was used, which indicates that removal of micro-organisms was not responsible for the reduction in the incidence of phlebitis. The remaining two studies (3,23) showing a clinical advantage for filters were double-blinded and used larger sample sizes than in the other four.

This study demonstrates the need for a filter which is capable of adsorbing microbial endotoxins, but not intravenous additives, thus relieving ward staff of the necessity of a daily filter change and preventing possible microbial contamination of the infusion system during this procedure. It also emphasizes the need for a limit test for particulate matter in small volume parenteral injections and for powders requiring reconstitution prior to injection.

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APPENDIX I

Instructions for use of filter

1) Insert needle adapter of administration set into filter inlet.

2) Holding the filter below the level of the infusion container, open the clamp of the IV administration set, and ensure the back (flat side) of the filter is completely filled.

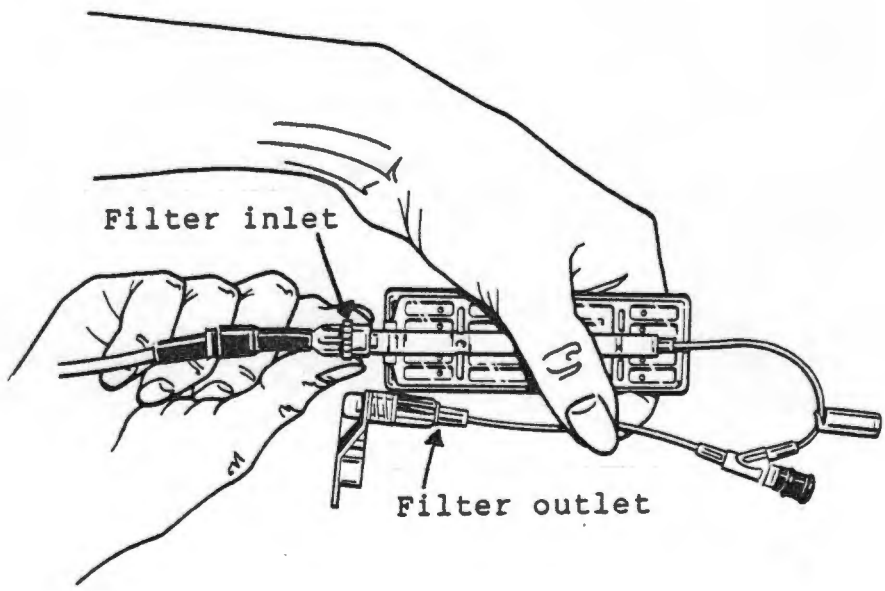
3) Close administration set clamp.

4) Rotate the filter to observe the front of the filter.

5) Remove the protective cap from the filter outlet and open the administration set clamp to prime filter and entire pathway, and ensure that air bubbles are absent.

6) Attach the filter outlet to the cannula.

Diagram of filter



APPENDIX II

Patient data collected

Hospital and ward

Patient's name and hospital number

Trial number

Infusion number

Filter or control group

Age

Race

Sex

Surgical procedure

Medical condition

Site of cannulation, where inserted and by whom

Type and size of cannula

Length of infusion in hours and reason for discontinuation

Daily phlebitis score

Time to phlebitis in hours

Time, date and reason for infusion set change

Time and date of filter change

Length of hospital stay

Oral medicines administered

Intravenous medicines administered

Intramuscular medicines administered

Intravenous fluids administered

Microbial contaminants isolated from skin

Microbial contaminants isolated from filters

Microbial contaminants isolated from cannula tips

Dressing over cannula

Alcohol intake

Smoking habits

PATIENT 001 Coloured Female Age 16 years Mass 47kg

DIAGNOSIS Pulmonary tuberculosis
Empyema
Drainage of lung abscess

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD		▨			
PHLEBITIS SCORE		0	0	0	0
TEMPERATURE	°C	38,2	37,3	37,3	37,5
PULSE RATE	.m	105	100	96	108
RESPIRATORY RATE	.m	35	38	24	30
BLOOD PRESSURE	mm Hg	120/80	120/80	130/90	120/60
E S R	mm.h	100	87	-	94
W B C COUNT	$x10^9$.ℓ	12,1	11,3	-	9,8
HAEMATOCRIT		,381	,359	-	,338
HAEMOGLOBIN	g.dℓ	12	12,3	-	11,3

MEDICINES
- 5d + Penicillin 2mu IV .6h
- 2d + Gentamicin 80mg IV .8h
- 5d + Metronidazole 400mg po .8h
- Morphine 2mgIV.h

INTRAVENOUS FLUIDS: RF | D5 | RF | M

TOTAL DURATION OF INFUSION: 3,4d*

OUTCOME: Final phlebitis score 0; Days to phlebitis N/A

* Elective removal of IV line.

Microbiology

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4) Discarded
Cannula) by
Swabs) ward staff

PATIENT 002 Coloured Male Age 50 years Mass 90kg

DIAGNOSIS Ventricular septal defect
Aortic incompetence secondary to bacterial endocarditis
Bacterial endocarditis - β haemolytic streptococcus
Gout
Essential hypertension
Chronic pyelonephritis
Renal failure - acute
Left ventricular failure

ALCOHOL INTAKE [4]
SMOKING [4]

Microbiology

1st Cannulation site		2nd Cannulation site	
Filter 1	i Cephalosporium species	Cannula	NG
	ii Aspergillus nidulans	Swabs	NG
Filter 2	NG		
Filter 3	NG		
Cannula	NG		
Swabs	NG		

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11
CANNULATION SITE		← 1st →			← 2nd →							
FILTER/CONTROL PERIOD		▨			▨							
PHLEBITIS SCORE		0	0	0	-	0	0	0	0	1+	1+	2+
TEMPERATURE	°C	35,9	36,3	36,1	36,1	36	36,2	36,3	36,5	36,4	36,3	36
PULSE RATE	.m	88	84	90	88	80	90	80	80	88	92	80
RESPIRATORY RATE	.m	28	24	24	20	22	24	24	28	24	24	20
BLOOD PRESSURE	mm Hg	130/80	130/80	140/80	140/70	130/60	130/70	130/60	140/60	130/80	120/80	130/50
E S R	mm.h	108	-	-	100	97	79	87	-	66	-	128
W B C COUNT	$x10^9$.ℓ	9	7,5	-	-	7,1	8	7,3	-	5,9	-	6,3
HAEMATOCRIT		,240	,279	-	-	,295	,350	,344	-	,286	-	,296
HAEMOGLOBIN	g.dℓ	9	9,1	-	-	9,7	11,6	10,2	-	9,2	-	9,9

MEDICINES
- 5d + Tobramycin 80mg IV .d
- 21d + Penicillin 2mu IV .6h
- 20mg IV, Furosemide 80mg po .d
- 44d + Diclophenac 50mg po tds

INTRAVENOUS FLUIDS: NS | NS

TOTAL DURATION OF INFUSION	1st Cannulation site	2nd Cannulation site
	3d*	6,8d
OUTCOME: Final phlebitis score	0	2+
Days to phlebitis	N/A	6,8

* Elective removal of IV line.

PATIENT 003 Coloured Male Age 57 years Mass 68kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae
Urethral stricture

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD					
PHLEBITIS SCORE		0	0	3+	3+
TEMPERATURE	°C	36	36,4	36	36,3
PULSE RATE	.m	74	74	80	68
RESPIRATORY RATE	.m	20	24	20	20
BLOOD PRESSURE	mm Hg	130/70	120/70	130/80	120/80
E S R	mm.h	115	81	-	-
W B C COUNT	$x10^9$.ℓ	12	8,1	-	-
HAEMATOCRIT		,354	,358	-	-
HAEMOGLOBIN	g.dℓ	11,8	11,8	-	-

MEDICINES 4d + Cefamandole 1,5g IV .8h

Microbiology

Cannula NG
Swabs NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 4d

OUTCOME Final phlebitis score 3+
Days to phlebitis 2,9

PATIENT 004 Black Male Age 31 years Mass 57kg

DIAGNOSIS Lobar pneumonia - Klebsiella pneumoniae

ALCOHOL INTAKE [4]
SMOKING [2]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD				
PHLEBITIS SCORE		0	0	0
TEMPERATURE	°C	37	37	36,3
PULSE RATE	.m	80	70	54
RESPIRATORY RATE	.m	24	22	20
BLOOD PRESSURE	mm Hg	120/70	120/70	110/70
E S R	mm.h	26	32	39
W B C COUNT	$x10^9$.ℓ	11	5	5,2
HAEMATOCRIT		,464	,390	,398
HAEMOGLOBIN	g.dℓ	15,5	14	13,4

MEDICINES Ceftazidime 1g IV .8h →
Paracetamol 1g po .6h prn →

Microbiology

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 2,7d*

OUTCOME Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line.

PATIENT 005 Coloured Male Age 23 years Mass 60kg

DIAGNOSIS Suspected pneumonia - final diagnosis not established

ALCOHOL INTAKE [2]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		←1st→			←2nd→		
FILTER/CONTROL PERIOD		//////	//////	//////	.....	.....	.....
PHLEBITIS SCORE		0	0	1+	0	0	2+
TEMPERATURE	°C	36	36,6	36,7	36,6	36,2	36,5
PULSE RATE	.m	60	58	70	70	76	70
RESPIRATORY RATE	.m	20	22	20	20	20	20
BLOOD PRESSURE	mm Hg	120/70	130/80	130/70	130/70	120/70	120/70
E S R	mm.h	12	10	12	-	11	-
W B C COUNT	x10⁹.ℓ	4,2	4,7	7,0	-	6,9	-
HAEMATOCRIT		,434	,407	,520	-	,440	-
HAEMOGLOBIN	g.dℓ	15,1	14,9	16,4	-	4,9	-

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

2nd Cannulation site

Cannula } Discarded by
Swabs } ward staff

MEDICINES
Cefamandole 1,5g IV .8h
Indomethacin 25mg po tds
Pethidine 50mg IM

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,8d*	2,8d
OUTCOME Final phlebitis score	1+	2+
Days to phlebitis	N/A	2,8

* Infusion discontinued due to local pain

PATIENT 006 Coloured Male Age 32 years Mass 59kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae

ALCOHOL INTAKE [3]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		←1st→		←2nd→		
FILTER/CONTROL PERIOD		.....	.....	//////	//////	//////
PHLEBITIS SCORE		0	3+	0	0	0
TEMPERATURE	°C	38,2	37	36,7	36,7	36,6
PULSE RATE	.m	80	80	76	70	80
RESPIRATORY RATE	.m	20	20	20	28	28
BLOOD PRESSURE	mm Hg	140/100	130/80	130/90	140/80	140/80
E S R	mm.h	-	-	46	35	52
W B C COUNT	x10⁹.ℓ	14,8	-	6,4	6,4	8,5
HAEMATOCRIT		,563	-	,391	,366	,375
HAEMOGLOBIN	g.dℓ	16,8	-	13,2	12,8	12,8

Microbiology

1st Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

MEDICINES
Cefamandole 1,5g IV .8h
Indomethacin 25mg po tds

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	1,4d	2,9d*
OUTCOME Final phlebitis score	3+	0
Days to phlebitis	1,4	N/A

* Elective removal of IV line.

PATIENT 007 Black Male Age 40 years Mass 67kg

DIAGNOSIS Lobar pneumonia - Klebsiella species
Pancreatitis
Chronic alcoholism

ALCOHOL INTAKE [5]
SMOKING [5]

DAY OF STUDY		1	2	3
CANNULATION SITE		←1st→	←2nd→	
FILTER/CONTROL PERIOD				
PHLEBITIS SCORE		3+	3+	4+
TEMPERATURE	°C	38,5	37,4	38,8
PULSE RATE	.m	112	108	120
RESPIRATORY RATE	.m	28	24	30
BLOOD PRESSURE	mm Hg	130/80	160/80	140/90
E S R	mm.h	95	-	88
W B C COUNT	$x10^9.\ell$	19,8	-	21,4
HAEMATOCRIT		,313	-	,263
HAEMOGLOBIN	g.dℓ	10,8	-	8,5

Microbiology

1st Cannulation site

Filter 1	NG
Cannula	NG
Swabs	NG

2nd Cannulation site

Cannula	NG
Swabs	NG

MEDICINES
- 5d + Cefamandole 1,5g IV .6h
- 5d + Metronidazole 400mg po tds

INTRAVENOUS FLUIDS M

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		1d	2d
OUTCOME	Final phlebitis score	3+	4+
	Days to phlebitis	1	1

PATIENT 008 Coloured Male Age 33 years Mass 51kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [3]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		←1st→						
FILTER/CONTROL PERIOD								
PHLEBITIS SCORE		0	1+	0	0	2+	3+	3+
TEMPERATURE	°C	39	36,8	36,3	36,4	36,2	36,5	37
PULSE RATE	.m	96	70	84	76	70	88	80
RESPIRATORY RATE	.m	38	28	24	28	24	24	20
BLOOD PRESSURE	mm Hg	130/80	140/80	150/80	130/90	130/60	130/90	120/80
E S R	mm.h	-	123	112	100	-	85	72
W B C COUNT	$x10^9.\ell$	-	10,8	7	9,3	-	9,9	10,1
HAEMATOCRIT		-	,383	,361	,330	-	,399	,384
HAEMOGLOBIN	g.dℓ	-	12,3	11,9	11,5	-	13,4	13,1

Microbiology

Cannula	NG
Swabs	NG

MEDICINES
- Cefamandole 1,5g IV .8h
- Indomethacin 25mg po tds
- Hexoprenaline Neb .4h

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION		6,5d
OUTCOME	Final phlebitis score	3+
	Days to phlebitis	4,6

PATIENT 009 Coloured Male Age 26 years Mass 55kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [4]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		←	1st		→	
FILTER/CONTROL PERIOD		▒▒▒	▒▒▒	▒▒▒	▒▒▒	
PHLEBITIS SCORE		0	0	0	1+	3+
TEMPERATURE	°C	36,4	36,4	36,6	36,5	36,5
PULSE RATE	.m	96	70	88	104	72
RESPIRATORY RATE	.m	30	30	40	32	30
BLOOD PRESSURE	mm Hg	110/60	120/80	100/70	140/90	110/60
E S R	mm.h	-	100	101	87	-
W B C COUNT	$x10^9$.ℓ	-	14,9	14,7	11,5	8,7
HAEMATOCRIT		-	,412	,331	,376	,383
HAEMOGLOBIN	g.dℓ	-	12,5	10,8	11,7	12,4

MEDICINES Ceftazidime 1g IV .8h

INTRAVENOUS FLUIDS NS | D5

TOTAL DURATION OF INFUSION 4,6d

OUTCOME Final phlebitis score 3+
Days to phlebitis 4,6

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

PATIENT 010 Coloured Female Age 22 years

DIAGNOSIS Bilateral pyosalpinx - bacteriological diagnosis not established

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2
CANNULATION SITE		← 1st →	
FILTER/CONTROL PERIOD		▒▒▒	▒▒▒
PHLEBITIS SCORE		1+	2+
TEMPERATURE	°C	37,3	37
PULSE RATE	.m	100	94
RESPIRATORY RATE	.m	24	-
BLOOD PRESSURE	mm Hg	120/80	-
E S R	mm.h	125	-
W B C COUNT	$x10^9$.ℓ	10,1	-
HAEMATOCRIT		,309	-
HAEMOGLOBIN	g.dℓ	10,4	-

MEDICINES Rolitetracycline 275mg IV .12h

INTRAVENOUS FLUIDS PB | M

TOTAL DURATION OF INFUSION 1,7d

OUTCOME Final phlebitis score 2+
Days to phlebitis 1,7

Microbiology

Cannula) Discarded by
Swabs) ward staff

PATIENT 011 Coloured Male Age 27 years

DIAGNOSIS Duodenal ulcer
Vagotomy
Gastro-jejunostomy

ALCOHOL INTAKE [1]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →		← 2nd →		
FILTER/CONTROL PERIOD		⋯		///		
PHLEBITIS SCORE		0	1+	3+ 0	0	2+
TEMPERATURE	°C	36,4	37,2	36,2	36,8	37
PULSE RATE	.m	84	72	76	70	72
RESPIRATORY RATE	.m	28	20	18	20	24
BLOOD PRESSURE	mm Hg	120/70	110/70	120/80	110/60	110/70
E S R	mm.h	5	24	-	40	42
W B C COUNT	x10⁹.ℓ	11,5	10,4	11	5,4	4,8
HAEMATOCRIT		,460	,390	,350	,357	,371
HAEMOGLOBIN	g.dℓ	14,5	13,3	11,9	12,4	12,4

Microbiology

1st Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site

Filter 1 NG
Filter 2 Staphylococcus epidermidis
Cannula Staphylococcus epidermidis
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES

INTRAVENOUS FLUIDS [PB | M]

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		2,4d	2,6d
OUTCOME	Final phlebitis score	3+	2+
	Days to phlebitis	2,4	2,4

PATIENT 012 Coloured Male Age 45 years

DIAGNOSIS Myocardial infarction
Angina pectoris

ALCOHOL INTAKE [4]
SMOKING [5]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →			
FILTER/CONTROL PERIOD		///	⋯				
PHLEBITIS SCORE		1+	1+	0	0	0	0
TEMPERATURE	°C	36	37,5	35,9	36,4	36,1	36,9
PULSE RATE	.m	100	112	90	82	78	90
RESPIRATORY RATE	.m	24	26	20	18	20	20
BLOOD PRESSURE	mm Hg	120/90	110/70	120/90	110/60	110/70	100/60
E S R	mm.h	30	32	32	38	-	40
W B C COUNT	x10⁹.ℓ	15,5	13,4	14,1	16,4	10,2	9,4
HAEMATOCRIT		,509	,520	,515	,470	,487	,461
HAEMOGLOBIN	g.dℓ	17	16,6	18	16,6	16	15,3

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 i ~~α~~ haemolytic streptococcus
ii Staphylococcus epidermidis
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 Staphylococcus epidermidis

MEDICINES

Isosorbide dinitrate 20mg po qid →
'Moduretic' po 2.d →
Paracetamol 1g po .6h prn →
Metoprolol 50mg po tds →
Diazepam 5mg po tds →
Morphine 2mg IV prn

INTRAVENOUS FLUIDS [NS]

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		1,5d*	4,5d*
OUTCOME	Final phlebitis score	1+	0
	Days to phlebitis	N/A	N/A

* Discontinued due to infiltration into tissues
* Elective removal of IV line

PATIENT 013 Coloured Male Age 30 years Mass 66kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [2]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		←———	1st	———	→		
FILTER/CONTROL PERIOD		//////	//////	//////	//////	//////	
PHLEBITIS SCORE		0	0	0	0	0	0
TEMPERATURE	°C	38,8	36,8	36,4	36,8	37	36,6
PULSE RATE	.m	112	90	80	90	84	92
RESPIRATORY RATE	.m	24	24	28	30	28	24
BLOOD PRESSURE	mm Hg	130/90	120/70	140/90	140/100	160/100	140/90
E S R	mm.h	129	120	136	-	139	-
W B C COUNT	$x10^9$.ℓ	27,7	19,4	18,2	15,9	17,6	-
HAEMATOCRIT		,342	,290	,338	,320	,316	-
HAEMOGLOBIN	g.dℓ	11,8	10,6	11,2	10	10,3	-

Microbiology

Filter	1	NG
Filter	2	NG
Filter	3	NG
Filter	4	NG
Filter	5	NG
Cannula		NG
Swab	1	Staphylococcus epidermidis
Swab	2	NG

MEDICINES
Ceftazidime 1g IV .8h
Potassium chloride 1,5g IV

INTRAVENOUS FLUIDS: NS | M | NS

TOTAL DURATION OF INFUSION 5,3d*

OUTCOME
Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line.

PATIENT 014 Coloured Male Age 32 years

DIAGNOSIS Fractured femur - compound
Sepsis - Proteus mirabilis

ALCOHOL INTAKE [4]
SMOKING [2]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		←———	1st	———	→
FILTER/CONTROL PERIOD		//////	//////	//////	//////
PHLEBITIS SCORE		0	0	0	0
TEMPERATURE	°C	36,9	36,6	36,2	36,4
PULSE RATE	.m	76	70	78	76
RESPIRATORY RATE	.m	20	18	24	20
BLOOD PRESSURE	mm Hg	120/70	120/80	120/70	110/80
E S R	mm.h	90	92	76	68
W B C COUNT	$x10^9$.ℓ	-	11,3	9,5	11,2
HAEMATOCRIT		-	,328	,345	,332
HAEMOGLOBIN	g.dℓ	-	11	10,9	10,7

Microbiology

Filter	1	NG
Filter	2	NG
Filter	3	NG
Filter	4	NG
Cannula		NG
Swabs		NG

MEDICINES
9d → Gentamicin 100mg IV .8h
62d → 'Panadeine' 2 po .6h prn
62d → Dextropropoxyphene 130mg po .6h prn

INTRAVENOUS FLUIDS: D5inNS | NS

TOTAL DURATION OF INFUSION 3,7d*

OUTCOME
Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line

PATIENT 015 Coloured Male Age 38 years

DIAGNOSIS Lung abscess - bacteriological diagnosis not established
Epilepsy
Chronic alcoholism

ALCOHOL INTAKE [5]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →	← 2nd →				← 3rd →			
FILTER/CONTROL PERIOD										
PHLEBITIS SCORE		2+	0	1+	1+	1+	0	1+	3+	3+
TEMPERATURE	°C	38	38,2	38,2	37	37,8	37,7	37	36,9	36,3
PULSE RATE	.m	100	90	100	80	88	92	88	80	60
RESPIRATORY RATE	.m	32	24	28	20	32	24	20	20	20
BLOOD PRESSURE	mm Hg	100/70	110/70	130/90	130/80	120/80	120/80	110/70	120/80	110/70
E S R	mm.h	-	114	118	106	107	100	110	95	98
W B C COUNT	$x10^9$.ℓ	17,4	14,5	17,2	17,9	15,3	15	10,9	9,9	8,6
HAEMATOCRIT		,352	,358	,338	,336	,326	,343	-	,316	,339
HAEMOGLOBIN	g.dℓ	11,6	11,5	11,4	11,2	11	11,8	11,9	10,5	11,3

Microbiology
1st Cannulation site
Cannula NG
Swabs NG
2nd Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Cannula NG
Swabs Staphylococcus epidermidis
3rd Cannulation site
Cannula NG
Swabs NG

MEDICINES
Penicillin 10mu IV .6h → 5mu IV .6h
Metronidazole 400mg po .8h
Indomethacin 25mg po tds
Phenytoin 300 mg po at night
Phenobarbitone 30mg po .8h

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION	0,9d	3,9d*	3,9d
OUTCOME: Final phlebitis score	2+	1+	3+
OUTCOME: Days to phlebitis	0,9	N/A	2,9

* Discontinued due to blockage of access line.

PATIENT 016 Coloured Male Age 35 years Mass 73kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →						
FILTER/CONTROL PERIOD								
PHLEBITIS SCORE		0	0	0	0	0	1+	1+
TEMPERATURE	°C	37,2	36,6	37,9	38,2	36,6	36,8	36,5
PULSE RATE	.m	110	84	80	100	92	100	80
RESPIRATORY RATE	.m	32	30	32	36	32	30	28
BLOOD PRESSURE	mm Hg	100/60	100/60	130/90	130/80	140/80	140/90	130/80
E S R	mm.h	86	101	91	105	32	105	108
W B C COUNT	$x10^9$.ℓ	13,2	7,5	10,3	10,7	10,1	6,7	6,32
HAEMATOCRIT		,408	,367	,366	,346	,385	,389	-
HAEMOGLOBIN	g.dℓ	14,2	11,9	12,5	11,8	13,4	13,7	13,5

Microbiology
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 Staphylococcus epidermidi
Cannula NG
Swabs Staphylococcus epidermidi

MEDICINES
Ceftazidime 1g IV .8h
Indomethacin 25mg po tds
Paracetamol 1g po tds prn

INTRAVENOUS FLUIDS: NS

TOTAL DURATION OF INFUSION	6,5d*
OUTCOME: Final phlebitis score	1+
OUTCOME: Days to phlebitis	N/A

* Discontinued due to blockage of access line and local pain.

PATIENT 017 Coloured Male Age 31 years Mass 60kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Brown Séquard syndrome

ALCOHOL INTAKE [5]
SMOKING [5]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD		[shaded]			
PHLEBITIS SCORE		0	1+	1+	1+
TEMPERATURE	°C	35,9	35,5	36,2	36,3
PULSE RATE	.m	60	68	76	80
RESPIRATORY RATE	.m	20	20	24	20
BLOOD PRESSURE	mm Hg	110/70	130/70	120/70	120/70
E S R	mm.h	21	17	10	6
W B C COUNT	x10⁹.ℓ	7,8	6,5	9,6	7,6
HAEMATOCRIT		,344	,340	-	,311
HAEMOGLOBIN	g.dℓ	11,4	11	12,9	10,4

MEDICINES 4d + Cefamandole 1,5g IV .8h
4d + Indomethacin 25mg po tds →

INTRAVENOUS FLUIDS [NS]

TOTAL DURATION OF INFUSION 3,1d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Elective removal of IV line.

Microbiology
Cannula NG
Swabs NG

PATIENT 018 Coloured Male Age 63 years Mass 69kg

DIAGNOSIS Cholelithiasis
Cholecystectomy
Hypertension

ALCOHOL INTAKE [1]
SMOKING [3]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD		[shaded]			
PHLEBITIS SCORE		0	0	2+	3+
TEMPERATURE	°C	37,6	37,5	36,4	36,6
PULSE RATE	.m	100	88	90	88
RESPIRATORY RATE	.m	24	20	24	20
BLOOD PRESSURE	mm Hg	170/90	150/90	190/110	170/90
E S R	mm.h	60	-	66	67
W B C COUNT	x10⁹.ℓ	11,8	-	9,8	7,4
HAEMATOCRIT		,342	-	,369	-
HAEMOGLOBIN	g.dℓ	11,8	-	12,5	14,9

MEDICINES 1d + Cefamandole 1g IV .6h
Dextropropoxyphene 130mg po .4h prn
Papaveretum 15mg IM.6h

INTRAVENOUS FLUIDS [PB] [M]

TOTAL DURATION OF INFUSION 3,9d

OUTCOME Final phlebitis score 2+
Days to phlebitis 2,8

Microbiology
Cannula) Discarded by
Swabs) ward staff

PATIENT 019 Coloured Male Age 57 years Mass 60kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Septicaemia - Escherichia coli; Acinetobacter species
Delirium tremens
Cirrhosis, with probable portal hypertension

ALCOHOL INTAKE [5]

SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
CANNULATION SITE		← 1st →					← 2nd →			← 3rd →						
FILTER/CONTROL PERIOD																
PHLEBITIS SCORE		0	0	0	0	0	3+	0	0	0	0	0	1+	1+	2+	2+
TEMPERATURE	°C	39	39,1	37,6	37,1	37,4	37,2	36,6	38,2	37,1	37,6	37	36,2	37,4	36,2	36,8
PULSE RATE	.m	120	136	120	112	100	104	100	120	112	110	90	104	100	90	90
RESPIRATORY RATE	.m	38	32	36	28	24	32	30	32	30	30	30	32	28	30	28
BLOOD PRESSURE	mm Hg	160/90	160/80	120/70	110/70	120/90	120/70	120/80	130/100	130/80	130/80	110/70	110/70	120/70	115/70	95/60
E S R	mm.h	121	71	88	84	72	69	78	70	75	70	80	66	56	59	64
W B C COUNT	$x10^9$.ℓ	8,9	8,5	7,2	6,6	7	7,2	13,1	8,7	7,9	8,6	7,2	5,6	5,5	4,2	6,2
HAEMATOCRIT		,373	,336	,335	,318	,302	,336	-	,324	,298	,320	,305	,298	-	,323	,334
HAEMOGLOBIN	g.dℓ	12,5	11,1	10,8	11,3	9,8	10,8	10	10	9,8	10,2	10,9	11,3	9,8	10,6	10,8

MEDICINES
- Penicillin 5mu IV .6h
- Gentamicin 110mg IV .6h
- Clothiapine 40mg IV .6h
- Thiamine 100mg IV .d
- Vitamin B Co 2 ml IV .d
- Vitamin K 10mg IV .d
- Potassium chloride 3g IV .8h
- 120mg IV .8h

INTRAVENOUS FLUIDS: NS

TOTAL DURATION OF INFUSION: 1st Cannulation site 5,8d; 2nd Cannulation site 2,6d*; 3rd Cannulation site 5,5d

OUTCOME: Final phlebitis score 3+; 0; 2+
Days to phlebitis 5,8d; N/A; 4,5

* Discontinued due to patient non-compliance.

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Cannula i Enterobacter species
ii Bacillus species
Swabs NG

2nd Cannulation site

Cannula) Discarded by
Swabs) patient

3rd Cannulation site

Cannula NG
Swab 1 i Bacillus species
ii Enterococcus species
Swab 2 NG

PATIENT 020 Black Male Age 48 years

DIAGNOSIS Pancreatitis - alcoholic

ALCOHOL INTAKE [5]
SMOKING [2]

DAY OF STUDY		1	2	3
CANNULATION SITE		←——— 1st ———→		
FILTER/CONTROL PERIOD		//////////	//////////	//////////
PHLEBITIS SCORE		0	0	2+
TEMPERATURE	°C	37,4	38,8	38
PULSE RATE	.m	88	88	82
RESPIRATORY RATE	.m	18	20	24
BLOOD PRESSURE	mm Hg	130/80	120/70	150/90
E S R	mm.h	32	52	68
W B C COUNT	$x10^9.\ell$	8,5	11,5	9,9
HAEMATOCRIT		,413	,376	,414
HAEMOGLOBIN	g.dℓ	13,7	14,1	14

MEDICINES Papaveretum 15mg IM .6h prn

INTRAVENOUS FLUIDS RF | M

TOTAL DURATION OF INFUSION 2,9d

OUTCOME
Final phlebitis score 2+
Days to phlebitis 2,9

Microbiology

Filter 1 NG
Filter 2 Staphylococcus epidermidis
Filter 3 Staphylococcus epidermidis
Cannula Staphylococcus epidermidis
Swabs Staphylococcus epidermidis

PATIENT 021 Black Female Age 32 years Mass 72 kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3
CANNULATION SITE		←——— 1st ———→	←2nd→	
FILTER/CONTROL PERIOD		.....	.....	
PHLEBITIS SCORE		0	2+	2+
TEMPERATURE	°C	37	36,1	36,3
PULSE RATE	.m	92	62	60
RESPIRATORY RATE	.m	18	20	18
BLOOD PRESSURE	mm Hg	110/70	130/90	100/70
E S R	mm.h	115	105	98
W B C COUNT	$x10^9.\ell$	15,5	7,2	7,7
HAEMATOCRIT		-	,339	,355
HAEMOGLOBIN	g.dℓ	11,5	11,6	12,1

MEDICINES
Ceftazidime 1g IV .8h →
Hexoprenaline Neb .8h →

INTRAVENOUS FLUIDS NS

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		1,7d	1d
OUTCOME	Final phlebitis score	2+	2+
	Days to phlebitis	1,4	1

Microbiology

1st Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site

Cannula NG
Swabs NG

PATIENT 022 Coloured Male Age 62 years Mass 50kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Chronic obstructive airways disease

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →					← 2nd →		
FILTER/CONTROL PERIOD									
PHLEBITIS SCORE		0	1+	1+	0	0	0	0	0
TEMPERATURE	°C	36,3	36,5	36,3	35,6	35,3	37,3	36,5	35,7
PULSE RATE	.m	80	82	90	90	92	88	88	80
RESPIRATORY RATE	.m	30	32	30	28	28	30	32	30
BLOOD PRESSURE	mm Hg	100/60	110/70	100/60	100/60	100/60	130/80	140/80	135/95
E S R	mm.h	58	45	45	55	65	64	65	68
W B C COUNT	$x10^9.\ell$	12,2	11,3	9,4	9,6	11,5	12,6	9,1	11,1
HAEMATOCRIT		,348	,343	,282	,290	,302	-	,277	,321
HAEMOGLOBIN	g.dℓ	11,4	11,3	9,1	10,6	10,6	9,3	9,3	10

Microbiology

1st Cannulation site

Cannula NG
Swabs NG

2nd Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

MEDICINES
- 1d + Penicillin 2mu IV .6h
- Cefamandole 1g IV .6h
- 1d + Indomethacin 25-50mg po tds
- Hexoprenaline Neb .4h
- Thiamine 100mg po .d
- Prednisone 40mg po .d

INTRAVENOUS FLUIDS: M | NS | D5 | NS

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		4,8d*	2,8d*
OUTCOME	Final phlebitis score	0	0
	Days to phlebitis	N/A	N/A

*Elective removal of IV line.

PATIENT 023 Black Male Age 44 years Mass 58 kg

DIAGNOSIS Pneumonia, necrotising - bacteriological diagnosis not established

Microbiology

1st Cannulation site

Filter 1,2,3,5,6 NG
Filter 4 Staphylococcus epidermidis
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 i Bacillus species
ii Penicillium species

2nd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

3rd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

ALCOHOL INTAKE [1]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11	12	13
CANNULATION SITE		← 1st →						← 2nd →			← 3rd →			
FILTER/CONTROL PERIOD														
PHLEBITIS SCORE		0	0	1+	2+	2+	2+	0	0	0	1+	3+	3+	3+
TEMPERATURE	°C	38,1	38	37,7	37	37	37	36,8	37,5	37,6	37	37	37,5	36,7
PULSE RATE	.m	118	110	108	100	110	80	76	90	100	96	92	96	100
RESPIRATORY RATE	.m	32	32	30	24	32	30	32	30	30	30	28	28	30
BLOOD PRESSURE	mm Hg	130/80	130/70	140/70	130/90	120/80	120/80	110/70	120/80	130/80	110/60	130/70	120/70	100/70
E S R	mm.h	150	-	150	130	-	125	-	-	-	-	148	150	150
W B C COUNT	$x10^9.\ell$	12,4	11,8	14,1	10,2	9,2	9,5	-	-	-	-	9,7	9,7	8,1
HAEMATOCRIT		,312	,298	,324	,316	,295	,300	-	-	-	-	,337	,322	,266
HAEMOGLOBIN	g.dℓ	10,5	9,9	10,7	10,1	9,7	9,4	-	-	-	-	10,5	9,8	8,6

MEDICINES
- Penicillin 5mu IV .6h
- Cefamandole 1g IV .6h
- Metronidazole 400mg po .8h
- Paracetamol 1g po tds

INTRAVENOUS FLUIDS: NS

		1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION		5,9d	2,9d*	3,9d
OUTCOME	Final phlebitis score	2+	0	3+
	Days to phlebitis	3,8	N/A	1,9

* Discontinued due to infiltration into tissues

PATIENT 024 Black Male Age 18 years Mass 46kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Previous pulmonary tuberculosis

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →					← 2nd →		
FILTER/CONTROL PERIOD		///	///	///	///	///	///	...	...
PHLEBITIS SCORE		0	0	0	0	0	3+	0	0
TEMPERATURE	°C	36,3	36,4	37,1	36,8	36,2	36,7	36	36,2
PULSE RATE	.m	62	64	62	64	60	60	58	72
RESPIRATORY RATE	.m	24	20	24	20	20	20	20	20
BLOOD PRESSURE	mm Hg	120/80	110/60	120/70	110/70	110/60	110/60	110/60	120/70
E S R	mm.h	92	79	62	67	62	57	60	51
W B C COUNT	$x10^9.\ell$	12,2	8,1	8,6	6,8	6,5	7,2	8,5	9
HAEMATOCRIT		,395	,361	,401	,409	,401	,438	-	,414
HAEMOGLOBIN	g.dℓ	14,2	12,9	13,4	13	13,2	14,1	13,3	13,6

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 Staphylococcus epidermidis
Filter 3 NG
Filter 4 i Proteus species
ii Staphylococcus epidermidis
Filter 5 NG
Filter 6 i Bacillus species
ii Staphylococcus epidermidis
Cannula NG
Swabs Staphylococcus epidermidis

2nd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES Cefamandole 1,5g IV .8h

INTRAVENOUS FLUIDS NS

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		5,5d	1,9d*
OUTCOME	Final phlebitis score	3+	0
	Days to phlebitis	5,5	N/A

* Elective removal of IV line.

PATIENT 025 Coloured Female Age 24 years Mass 64kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Bronchial asthma
Drug allergy - cefamandole

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →	← 2nd →	
FILTER/CONTROL PERIOD		///	///	///
PHLEBITIS SCORE		0	0	2+
TEMPERATURE	°C	38,4	36,2	37,1
PULSE RATE	.m	120	92	100
RESPIRATORY RATE	.m	28	24	30
BLOOD PRESSURE	mm Hg	110/60	130/80	130/70
E S R	mm.h	78	-	78
W B C COUNT	$x10^9.\ell$	10,4	10,4	9,8
HAEMATOCRIT		,377	,427	,390
HAEMOGLOBIN	g.dℓ	13,2	14,3	12,6

Microbiology

1st Cannulation site

Filter 1 NG
Cannula NG
Swab 1 Bacillus species
Swab 2 NG

2nd Cannulation site

Filter 1 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES Cefamandole 1,5g IV .8h
Indomethacin 25mg po tds
Hexoprenaline Neb .4h

INTRAVENOUS FLUIDS D5 M

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		1,6d*	0,9d
OUTCOME	Final phlebitis score	0	2+
	Days to phlebitis	N/A	0,9

* Discontinued due to infiltration into tissues

PATIENT 026 White Male Age 58 years Mass 61kg

DIAGNOSIS Sézary syndrome - T cell tumour

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	1	2	3	4
CANNULATION SITE		← 1st →			← 2nd →			
FILTER/CONTROL PERIOD		▒▒▒			///			
PHLEBITIS SCORE		0	0	0	0	0	1+	1+
TEMPERATURE	°C	36,3	37,2	37	36,4	36,3	36,2	35,8
PULSE RATE	.m	84	80	80	80	76	80	68
RESPIRATORY RATE	.m	18	20	18	-	20	18	20
BLOOD PRESSURE	mm Hg	150/60	150/70	120/70	130/70	130/90	140/70	160/90
E S R	mm.h	6	5	-	-	-	-	-
W B C COUNT	x10⁹.ℓ	14,7	10,8	-	14,1	-	-	-
HAEMATOCRIT		,368	,331	-	-	-	-	-
HAEMOGLOBIN	g.dℓ	12,2	11,5	-	11,4	-	-	-
MEDICINES		2'DCF 30mg IV .d →						

Microbiology

1st Cannulation site

Cannula i Staphylococcus aureus
ii Enterococcus species
Swab 1 i Staphylococcus aureus
ii Enterococcus species
iii Corynebacterium species
Swab 2 i Staphylococcus aureus
ii Enterococcus species

2nd Cannulation site

Filter 1 Staphylococcus epidermidis
Filter 2 NG
Filter 3 i Staphylococcus aureus
ii Staphylococcus epidermidis
Filter 4 NG
Cannula i Staphylococcus epidermidis
ii Micrococcus lutea
Swab 1 Enterococcus species
Swab 2 NG

INTRAVENOUS FLUIDS	NS	M	
		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		3d*	3,1d*
OUTCOME	Final phlebitis score	0	1+
	Days to phlebitis	N/A	N/A

* Elective removal of IV line

PATIENT 027 Coloured Male Age 38 years Mass 69kg

DIAGNOSIS Lobar pneumonia, bilateral - bacteriological diagnosis not established
Chronic alcoholism

ALCOHOL INTAKE [5]
SMOKING [3]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD		///		
PHLEBITIS SCORE		0	0	0
TEMPERATURE	°C	39	38,3	37,4
PULSE RATE	.m	100	104	100
RESPIRATORY RATE	.m	24	20	28
BLOOD PRESSURE	mm Hg	130/80	120/75	130/80
E S R	mm.h	84	120	123
W B C COUNT	x10⁹.ℓ	8,5	7,2	8,7
HAEMATOCRIT		,409	,383	,377
HAEMOGLOBIN	g.dℓ	13,7	12,6	12,2
MEDICINES		Cefamandole 1,5g IV .8h →		
		Clothiapine 40mg IV .8h →		
		Vitamin B Co 2ml IV .d →		

Microbiology

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swab 1 Corynebacterium species
Swab 2 Staphylococcus aureus

INTRAVENOUS FLUIDS	NS D5 in NS NS	
TOTAL DURATION OF INFUSION		2,3d*
OUTCOME	Final phlebitis score	0
	Days to phlebitis	N/A

* Discontinued due to blockage of access line.

PATIENT 028 Coloured Female Age 39 years

DIAGNOSIS Pelvic inflammatory disease - bacteriological diagnosis not established

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2
CANNULATION SITE		←1st→	
FILTER/CONTROL PERIOD		▨	▨
PHLEBITIS SCORE		0	0
TEMPERATURE	°C	36,8	38,4
PULSE RATE	.m	100	92
RESPIRATORY RATE	.m	32	32
BLOOD PRESSURE	mm Hg	130/90	110/70
E S R	mm.h	37	48
W B C COUNT	x10⁹.ℓ	12,4	8,8
HAEMATOCRIT		,431	,412
HAEMOGLOBIN	g.dℓ	14,7	13,9

Microbiology

Filter 1 NG
Filter 2 Staphylococcus epidermidis
Cannula NG
Swabs NG

MEDICINES
Penicillin 5mu IV .6h
Rolitetracycline 275mg IV .12h
Co-trimoxazole 2 po bd
Aspirin 600mg po .4h prn

INTRAVENOUS FLUIDS [M]

TOTAL DURATION OF INFUSION 1,8d*

OUTCOME Final phlebitis score 0
Days to phlebitis N/A

* Discontinued due to blockage of access line.

PATIENT 029 Coloured Male Age 41 years Mass 49kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae
Chronic obstructive airways disease

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		←1st→								
FILTER/CONTROL PERIOD		▨	▨	▨	▨	▨	▨	▨	▨	▨
PHLEBITIS SCORE		0	0	1+	1+	1+	1+	0	0	2+
TEMPERATURE	°C	36,7	37,8	37,8	37	36,5	37,4	37	37,1	36,9
PULSE RATE	.m	90	100	110	96	88	90	100	90	100
RESPIRATORY RATE	.m	24	32	32	24	24	28	28	30	30
BLOOD PRESSURE	mm Hg	110/70	120/70	120/80	110/60	130/80	130/80	110/60	120/70	120/65
E S R	mm.h	87	94	110	80	75	65	67	62	55
W B C COUNT	x10⁹.ℓ	18,9	15,3	16,4	17,1	16,1	13,6	13,6	15,4	12,7
HAEMATOCRIT		,371	,364	,367	,360	,365	,400	,396	,380	,363
HAEMOGLOBIN	g.dℓ	12	11,7	12,1	11,8	11,5	11,8	13	12,5	12,7

Microbiology

Cannula) Discarded by
Swabs) ward staff

MEDICINES
Penicillin 2mu IV .6h
Aminophylline 250mg IV .6h
Co-trimoxazole 2 po bd
Hexoprenaline Neb .6h
Dextropropoxyphene 130mg po tds prn
Metronidazole 400 mg po tds

INTRAVENOUS FLUIDS
NS

TOTAL DURATION OF INFUSION 8,9d

OUTCOME Final phlebitis score 2+
Days to phlebitis 8,9

PATIENT 030 Black Male Age 30 years

DIAGNOSIS Lung abscess - bacteriological diagnosis not established

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →		← 2nd →				
FILTER/CONTROL PERIOD		▨		▨				
PHLEBITIS SCORE		1+	1+	0	2+	3+	3+	3+
TEMPERATURE	°C	38	37	36,3	36,4	36,4	36,2	36
PULSE RATE	.m	84	70	76	60	60	60	76
RESPIRATORY RATE	.m	24	20	24	20	20	20	24
BLOOD PRESSURE	mm Hg	110/70	-	100/50	80/50	100/60	100/50	100/50
E S R	mm.h	-	148	-	-	-	-	-
W B C COUNT	x10⁹.ℓ	10,3	7,5	-	-	-	-	-
HAEMATOCRIT		,314	,297	-	-	-	-	-
HAEMOGLOBIN	g.dℓ	10,3	9,3	-	-	-	-	-

MEDICINES
Penicillin 5mu IV .6h
Metronidazole 400mg po .8h

INTRAVENOUS FLUIDS: NS

TOTAL DURATION OF INFUSION: 1st Cannulation site 2d* | 2nd Cannulation site 4,7d

OUTCOME
Final phlebitis score: 1st Cannulation site 1+ | 2nd Cannulation site 3+
Days to phlebitis: 1st Cannulation site N/A | 2nd Cannulation site 1,7

Microbiology

1st Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

* Discontinued due to blockage of access line

PATIENT 031 Black Male Age 38 years Mass 43kg

DIAGNOSIS Pneumonia - Klebsiella pneumoniae
Renal failure, acute

ALCOHOL INTAKE [5]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →					← 2nd →		
FILTER/CONTROL PERIOD		▨					▨		
PHLEBITIS SCORE		0	1+	1+	1+	2+	2+	1+	2+
TEMPERATURE	°C	36,4	36	36,2	36,9	36,7	36,4	36,2	36
PULSE RATE	.m	80	88	80	80	84	80	80	60
RESPIRATORY RATE	.m	32	24	28	32	20	24	20	20
BLOOD PRESSURE	mm Hg	140/80	140/90	150/90	180/110	160/110	170/100	140/80	160/100
E S R	mm.h	141	148	140	148	145	147	142	137
W B C COUNT	x10⁹.ℓ	19,5	14,8	15,6	25,2	25,9	22,2	21,3	20,9
HAEMATOCRIT		,275	,285	,282	,289	,285	,250	,252	,250
HAEMOGLOBIN	g.dℓ	8,9	8,9	9,2	8,8	9,1	7,5	8,4	8,2

MEDICINES
Cefamandole 1,5g IV .8 -12h
Thiamine 100mg po .d
Vitamin B Co po 2bd
Methyldopa 250mg po bd

INTRAVENOUS FLUIDS: NS | D5 | M

TOTAL DURATION OF INFUSION: 1st Cannulation site 5,5d | 2nd Cannulation site 1,8d

OUTCOME
Final phlebitis score: 1st Cannulation site 2+ | 2nd Cannulation site 2+
Days to phlebitis: 1st Cannulation site 4,4 | 2nd Cannulation site 1,8

Microbiology

1st Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site
Cannula) Discarded by
Swabs) ward staff

PATIENT 032 Coloured Male Age 66 years Mass 55kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Chronic obstructive airways disease
Myocardial infarction
Septic lesion in groin - Staphylococcus aureus

ALCOHOL INTAKE [4]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →					
FILTER/CONTROL PERIOD							
PHLEBITIS SCORE		0	0	3+	3+	3+	3+
TEMPERATURE	°C	37,4	37,2	36,8	36,5	36	36
PULSE RATE	.m	70	84	88	80	82	80
RESPIRATORY RATE	.m	20	24	24	24	20	20
BLOOD PRESSURE	mm Hg	120/60	140/80	120/60	130/80	120/60	110/50
E S R	mm.h	35	50	60	-	25	33
W B C COUNT	x10⁹.ℓ	9,4	8,8	9,7	7	5,3	4,7
HAEMATOCRIT		,299	-	,302	,325	,319	,340
HAEMOGLOBIN	g.dℓ	9,4	9,3	9,4	10,5	10,8	11,4

MEDICINES
2d + Penicillin 2,5mu IV .6h →
2d + Salbutamol Neb .4h →
'Kloref' 1 po bd

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 5,9d

OUTCOME Final phlebitis score 3+
Days to phlebitis 2,9

Microbiology
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

PATIENT 033 Black Male Age 45 years Mass 43kg

DIAGNOSIS Lung abscess - Bacteroides species isolated

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →		← 2nd →				← 3rd →	
FILTER/CONTROL PERIOD									
PHLEBITIS SCORE		1+	1+	0	3+	3+	3+	1+	1+
TEMPERATURE	°C	38,8	38	38	38,4	37,8	37	38,3	37,5
PULSE RATE	.m	100	92	90	100	92	100	100	80
RESPIRATORY RATE	.m	32	36	36	36	32	36	36	32
BLOOD PRESSURE	mm Hg	120/70	110/70	130/70	130/80	125/80	150/100	120/90	130/75
E S R	mm.h	>150	>150	>150	-	-	-	146	>150
W B C COUNT	x10⁹.ℓ	17,7	18,6	21,1	-	-	16,4	19,1	17,9
HAEMATOCRIT		,325	,365	,343	-	-	,358	,324	,324
HAEMOGLOBIN	g.dℓ	10,7	11,1	11,4	-	-	11,2	10,6	10,7

MEDICINES
Penicillin 5mu IV .6h →
Tobramycin 80mg IV .8h →
Metronidazole 800mg po .8h

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION	1,8d*	4d	1,6d*
OUTCOME Final phlebitis score	1+	3+	1+
Days to phlebitis	N/A	1,8	N/A

Microbiology
1st Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swab 1 NG
Swab 2 Enterococcus species
2nd Cannulation site
Cannula NG
Swabs NG
3rd Cannulation site
Filter 1 NG
Filter 2 NG
Cannula NG
Swabs NG

* Discontinued due to blockage of access line

PATIENT 034 Black Female Age 15 years Mass 47kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →							
FILTER/CONTROL PERIOD		▨							
PHLEBITIS SCORE		1+	1+	0	1+	1+	1+	2+	2+
TEMPERATURE	°C	37,1	36,5	36,6	37	36,9	37	36,9	36,7
PULSE RATE	.m	84	80	72	80	80	92	84	80
RESPIRATORY RATE	.m	24	20	32	24	28	24	20	24
BLOOD PRESSURE	mm Hg	130/80	110/60	100/60	120/80	110/70	110/70	110/70	110/60
E S R	mm.h	-	86	82	83	-	80	79	80
W B C COUNT	x10⁹.ℓ	13,5	8,9	8,4	9,3	-	10,9	9,1	8,4
HAEMATOCRIT		,326	,312	,330	,331	-	,340	,309	,334
HAEMOGLOBIN	g.dℓ	10,9	11,2	11,2	10,7	-	11,4	10,2	10,8

Microbiology

Filter 1	NG
Filter 2	NG
Filter 3	NG
Filter 4	NG
Filter 5	NG
Filter 6	NG
Filter 7	NG
Filter 8	NG
Cannula	NG
Swabs	NG

MEDICINES
Penicillin 2mu IV .6h
Metronidazole 500mg IV .8h
Gentamicin 40mg IV .8h

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 7,7d

OUTCOME
Final phlebitis score 2+
Days to phlebitis 6,6

PATIENT 035 Black Male Age 13 years Mass 31kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Pleural effusion

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →			← 2nd →			← 3rd →	
FILTER/CONTROL PERIOD		▨			⋯			▨	
PHLEBITIS SCORE		0	1+	2+	2+	1+	1+	1+	2+
TEMPERATURE	°C	39,2	37,7	38	38,5	37,7	37,4	37,7	37,7
PULSE RATE	.m	100	96	92	100	110	100	98	108
RESPIRATORY RATE	.m	30	28	24	30	28	28	36	32
BLOOD PRESSURE	mm Hg	120/70	110/50	90/50	100/60	110/70	110/70	110/70	120/70
E S R	mm.h	65	72	69	73	70	65	79	79
W B C COUNT	x10⁹.ℓ	8,3	9,1	7,4	10,3	8	14,3	7,7	7,5
HAEMATOCRIT		,349	,319	,310	,348	,352	,330	,313	,330
HAEMOGLOBIN	g.dℓ	11,8	11,1	10,6	11	11,9	10,4	10,6	11

Microbiology

1st Cannulation site

Filter 1	NG
Filter 2	NG
Filter 3	NG
Filter 4	NG
Cannula	Staphylococcus epidermidi
Swabs	NG

2nd Cannulation site

Cannula	Staphylococcus epidermidi
Swabs	NG

3rd Cannulation site

Filter 1	NG
Cannula	NG
Swabs	NG

MEDICINES
Gentamicin 40mg IV .8h
Penicillin 2mu IV .6h
Metronidazole 500mg IV .8h

INTRAVENOUS FLUIDS NS

		1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION		3,5d	2,5d*	1,3d
OUTCOME	Final phlebitis score	2+	1+	2+
	Days to phlebitis	2,5	N/A	1,3

* Discontinued due to blockage of access line

PATIENT 036 Coloured Male Age 13 years Mass 40kg

DIAGNOSIS Meningitis - probably viral

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD				
PHLEBITIS SCORE		1+	1+	2+
TEMPERATURE	°C	38	36,6	36,8
PULSE RATE	.m	80	80	88
RESPIRATORY RATE	.m	20	18	20
BLOOD PRESSURE	mm Hg	100/60	110/60	110/60
E S R	mm.h	18	17	19
W B C COUNT	$x10^9.\ell$	5,2	3,8	4,3
HAEMATOCRIT		,347	,372	,430
HAEMOGLOBIN	g.dℓ	12,1	12,4	13,8

MEDICINES
Penicillin 2mu IV .6h
Chloramphenicol 500mg IV .6h

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 3d

OUTCOME
Final phlebitis score 2+
Days to phlebitis 2,7

Microbiology
Cannula NG
Swabs NG

PATIENT 037 Black Female Age 23 years Mass 67kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →			
FILTER/CONTROL PERIOD							
PHLEBITIS SCORE		0	1+	2+	2+	2+	2+
TEMPERATURE	°C	37	37,5	36,4	36,7	37	36,7
PULSE RATE	.m	110	92	84	92	96	104
RESPIRATORY RATE	.m	24	20	20	24	20	24
BLOOD PRESSURE	mm Hg	110/60	100/50	110/70	120/70	130/90	110/60
E S R	mm.h	122	-	103	108	123	114
W B C COUNT	$x10^9.\ell$	10,2	-	7,8	10	14	8,2
HAEMATOCRIT		,280	-	,336	,351	,340	298
HAEMOGLOBIN	g.dℓ	9,7	-	10,9	11,5	11,2	9,8

MEDICINES
Penicillin 2mu IV .6h →
Paracetamol 1g po .4h prn →

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,6d	2,9d
OUTCOME		
Final phlebitis score	2+	2+
Days to phlebitis	2,4	0,9

Microbiology

1st Cannulation site
Filter 1 NG
Filter 2 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site
Cannula NG
Swabs NG

PATIENT 038 Coloured Male Age 29 years Mass 58kg

DIAGNOSIS Meningitis - probably viral

ALCOHOL INTAKE [6]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →		← 2nd →					← 3rd →	
FILTER/CONTROL PERIOD										
PHLEBITIS SCORE		0	0	0	0	1+	1+	0	0	0
TEMPERATURE	°C	37,5	36,7	36,6	36,2	35,9	36	35,9	36	36,1
PULSE RATE	.m	72	72	80	96	90	72	64	80	68
RESPIRATORY RATE	.m	18	20	24	24	20	28	20	28	24
BLOOD PRESSURE	mm Hg	130/90	120/70	120/80	120/70	120/70	120/70	120/80	110/70	120/80
E S R	mm.h	7	8	9	5	7	5	3	4	3
W B C COUNT	x10⁹.ℓ	7,1	8	21,3	14,9	7	8,9	7,6	8,8	8,6
HAEMATOCRIT		,448	,465	,699	,460	,434	,463	,462	,455	,449
HAEMOGLOBIN	g.dℓ	15,7	15,1	16,4	15,9	15	15,6	15,2	15,4	15,1

MEDICINES
Penicillin 2,5mu IV .6h
Chloramphenicol 500mg IV .6h
Paracetamol 1g po .6h prn

Microbiology

1st Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

2nd Cannulation site
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

3rd Cannulation site
Filter 1 NG
Filter 2 NG
Cannula NG
Swabs NG

INTRAVENOUS FLUIDS: NS | RF | NS

	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION	1,8d*	4,9d*	1,8d*
OUTCOME — Final phlebitis score	0	0	0
OUTCOME — Days to phlebitis	N/A	N/A	N/A

* Discontinued due to blockage of access line
° Elective removal of IV line

PATIENT 039 Coloured Male Age 52 years Mass 72kg

DIAGNOSIS Lung abscess - Staphylococcus aureus

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →		← 2nd →		
FILTER/CONTROL PERIOD						
PHLEBITIS SCORE		0	0	0	0	0
TEMPERATURE	°C	37,6	36,6	36	36,7	37
PULSE RATE	.m	92	88	96	88	92
RESPIRATORY RATE	.m	18	20	28	30	24
BLOOD PRESSURE	mm Hg	120/80	140/100	130/90	140/90	120/70
E S R	mm.h	-	-	145	145	-
W B C COUNT	x10⁹.ℓ	-	-	12,2	12,3	-
HAEMATOCRIT		-	-	,334	,324	-
HAEMOGLOBIN	g.dℓ	-	-	11,2	10,9	-

MEDICINES
5d + Penicillin 5mu IV .6h
5d + Metronidazole 800mg po .8h
4d + Indomethacin 25mg po tds

Microbiology

1st Cannulation site
Cannula) Discarded by
Swabs) ward staff

2nd Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3) Discarded
Cannula) by
Swabs) ward staff

INTRAVENOUS FLUIDS: NS | RF

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2d*	3d*
OUTCOME — Final phlebitis score	0	0
OUTCOME — Days to phlebitis	N/A	N/A

* Discontinued due to blockage of access line

PATIENT 040 Coloured Male Age 60 years Mass 49kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [4]
SMOKING [5]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →				← 2nd →				
FILTER/CONTROL PERIOD		▒▒▒	▒▒▒	▒▒▒	▒▒▒	///	///	///	///	///
PHLEBITIS SCORE		2+	2+	3+	3+	0	0	0	3+	3+
TEMPERATURE	°C	37,6	37,6	37,6	36,7	37	37,1	37	37,2	37
PULSE RATE	.m	100	88	92	80	68	82	72	92	80
RESPIRATORY RATE	.m	30	28	32	28	24	28	28	24	20
BLOOD PRESSURE	mm Hg	110/70	120/70	120/70	130/70	120/70	120/80	130/70	120/70	120/70
E S R	mm.h	-	126	122	122	120	119	110	82	118
W B C COUNT	x10⁹.ℓ	22,1	17	13,7	15,2	12	12,3	10,5	9,9	12
HAEMATOCRIT		-	,318	,329	,318	,298	,298	,293	,340	,297
HAEMOGLOBIN	g.dℓ	10	10,4	10,6	10	9,5	9,7	9,3	9,2	9,6

MEDICINES
Ceftazidime 1g IV .8h
Paracetamol 1g po .6h prn

Microbiology

1st Cannulation site
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Cannula NG
Swab 1 i Staphylococcus epidermidis
ii Enterococcus species
Swab 2 i Staphylococcus epidermidis
ii Enterococcus species

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	3,8d	4,9d
OUTCOME: Final phlebitis score	2+	3+
Days to phlebitis	0,9	4

PATIENT 041 Coloured Female Age 18 years Mass 39kg

DIAGNOSIS Mitral valve disease - rheumatic fever
Previous mitral valve replacement
Bacterial endocarditis - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →			← 2nd →			
FILTER/CONTROL PERIOD		▒▒▒	▒▒▒	▒▒▒	///	///	///	///
PHLEBITIS SCORE		0	0	0	0	0	0	2+
TEMPERATURE	°C	37,4	36,8	36,4	36,3	36,5	36,8	37
PULSE RATE	.m	120	108	80	110	120	120	120
RESPIRATORY RATE	.m	28	32	28	28	28	30	30
BLOOD PRESSURE	mm Hg	100/60	110/70	120/60	100/50	100/60	120/60	120/60
E S R	mm.h	-	-	20	-	-	-	-
W B C COUNT	x10⁹.ℓ	11,8	12,2	9,6	-	-	-	-
HAEMATOCRIT		,334	,334	,276	-	-	-	-
HAEMOGLOBIN	g.dℓ	10	10,3	8,9	-	-	-	-

MEDICINES
Penicillin 4mu IV .4h
Tobramycin 80mg IV .8h
'Moduretic' 2 po .d
Digoxin 0,25mg po .d

Microbiology

1st Cannulation site
Cannula NG
Swabs NG

2nd Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 Staphylococcus epidermidis
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,5d*	4,3d
OUTCOME: Final phlebitis score	0	2+
Days to phlebitis	N/A	4

* Discontinued due to blockage of access line

PATIENT 042 Coloured Male Age 49 years

DIAGNOSIS Chronic obstructive airways disease
Pulmonary emphysema with bullae
Pneumothorax

ALCOHOL INTAKE [2]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →				
FILTER/CONTROL PERIOD		~				
PHLEBITIS SCORE		0	1+	1+	3+	3+
TEMPERATURE	°C	36,2	39	36,6	36,2	36,5
PULSE RATE	.m	80	110	100	84	80
RESPIRATORY RATE	.m	28	24	20	20	24
BLOOD PRESSURE	mm Hg	110/60	110/70	115/70	110/80	110/80
E S R	mm.h	9	-	6	8	-
W B C COUNT	$x10^9$.ℓ	-	9,4	9,9	9,5	-
HAEMATOCRIT		-	,530	,507	,485	-
HAEMOGLOBIN	g.dℓ	-	16,6	16,4	15,4	-

Microbiology

Cannula NG
Swab 1 i Staphylococcus epidermidis
ii Bacillus species
Swab 2 NG

MEDICINES
Aminophylline 250 - 500mg IV .12h →
Amoxycillin 250mg po .8h →
'Moduretic' 2 po bd →
Hexoprenaline Neb .4h →

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 4,8d

OUTCOME
Final phlebitis score 3+
Days to phlebitis 3,4

PATIENT 043 Coloured Male Age 41 years Mass 50kg

DIAGNOSIS Bacterial endocarditis - bacteriological diagnosis not established
Mitral incompetence
Hypertension with renal impairment

ALCOHOL INTAKE [4]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →			← 2nd →					
FILTER/CONTROL PERIOD		///	///	///	~	~	~	~	~	
PHLEBITIS SCORE		0	0	0	0	1+	1+	0	2+	2+
TEMPERATURE	°C	36,5	36,5	36,3	36,9	36,2	36,1	36	36,4	-
PULSE RATE	.m	92	100	82	80	84	88	80	72	-
RESPIRATORY RATE	.m	24	28	24	24	20	24	24	20	-
BLOOD PRESSURE	mm Hg	160/90	140/80	160/100	160/110	160/100	150/80	140/80	170/100	-
E S R	mm.h	95	102	105	106	102	112	110	74	-
W B C COUNT	$x10^9$.ℓ	6,4	6,4	7,2	6,2	6,4	5	5,7	6,1	-
HAEMATOCRIT		,231	,240	,254	,253	,239	,269	,256	,239	-
HAEMOGLOBIN	g.dℓ	7,5	7,5	8	8,3	7,6	8,3	8,2	7,8	-

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

2nd Cannulation site

Cannula NG
Swabs NG

MEDICINES
20d +Penicillin 5mu IV .6h →
20d +Furosemide 80mg po .d →
20d +Prazosin 6 - 8mg po .d →
4d +'Slow K' 2 po tds →

INTRAVENOUS FLUIDS D5 | NS | D5 | NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,9d*	5,3d
OUTCOME: Final phlebitis score	0	2+
Days to phlebitis	N/A	4,9

* Discontinued due to blockage of access line

PATIENT 044 Black Male Age 36 years Mass 40kg

DIAGNOSIS Pancreatitis, chronic relapsing
Chronic alcoholism
Delirium tremens

ALCOHOL INTAKE [5]
SMOKING [5]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →		← 2nd →		
FILTER/CONTROL PERIOD		▨		▩		
PHLEBITIS SCORE		0	0	0	0	0
TEMPERATURE	°C	36,8	37,2	35,5	36,2	36
PULSE RATE	.m	76	72	72	76	60
RESPIRATORY RATE	.m	28	32	20	24	20
BLOOD PRESSURE	mm Hg	150/90	130/80	120/80	140/70	120/70
E S R	mm.h	-	115	-	90	100
W B C COUNT	x10⁹.ℓ	-	9,6	-	8	8,5
HAEMATOCRIT		-	,387	-	,318	,321
HAEMOGLOBIN	g.dℓ	-	12,6	-	10,1	10,4

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2) Discarded
Cannula) by
Swabs) patient

2nd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES

Penicillin 2mu IV .6h
Tobramycin 80mg IV .8h
Clothiapine 40mg IV .6h | 40mg po tds
Vitamin B Co 2ml IV .d
Aspirin 2 po .6h

INTRAVENOUS FLUIDS: NS | M | NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	1,8d*	2,5d°
OUTCOME Final phlebitis score	0	0
Days to phlebitis	N/A	N/A

* Discontinued due to patient non-compliance
° Discontinued due to infiltration into tissues

PATIENT 045 Black Male Age 56 years Mass 50kg

DIAGNOSIS Lung abscess - bacteriological diagnosis not established
Bronchiectasis

Microbiology

1st Cannulation site

Cannula NG
Swabs NG

2nd Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Filter 7 NG
Cannula NG
Swabs NG

ALCOHOL INTAKE [5]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11	12	13	1
CANNULATION SITE		← 1st →								← 2nd →					
FILTER/CONTROL PERIOD		▨							▩						
PHLEBITIS SCORE		0	0	0	1+	0	0	2+	3+	0	0	0	1+	3+	3+
TEMPERATURE	°C	38	36,3	36	36	36,3	35,6	35,9	36,4	36,5	36,3	36	36,2	36	35,7
PULSE RATE	.m	120	100	100	92	84	72	70	82	72	70	80	74	80	72
RESPIRATORY RATE	.m	24	28	24	28	24	24	24	28	24	28	20	20	24	24
BLOOD PRESSURE	mm Hg	140/90	120/70	110/70	140/90	120/60	120/60	140/90	120/70	130/90	130/90	120/80	130/80	140/90	140/
E S R	mm.h	90	90	95	93	87	78	81	74	100	91	90	88	-	95
W B C COUNT	x10⁹.ℓ	8,2	5,5	6,8	6,7	7,7	5,8	6,3	6,1	5,9	7,1	6,9	6,3	-	7
HAEMATOCRIT		,289	,289	,286	,256	,272	,277	,259	,270	,260	,265	,266	,290	-	,295
HAEMOGLOBIN	g.dℓ	8,5	8,5	9,2	7,7	8,5	8,5	8,3	8,2	7,9	8,3	7,7	8,9	-	9,1

MEDICINES

Penicillin 2mu IV .6h
Gentamicin 80mg IV .8h
Metronidazole 400mg po .8h
Aspirin 600mg po .6h

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	7,4d	5,9d
OUTCOME Final phlebitis score	3+	3+
Days to phlebitis	6,2	4,9

PATIENT 046 Black Male Age 31 years Mass 52kg

DIAGNOSIS Tuberculous meningitis

ALCOHOL INTAKE [1]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →	← 2nd →				← 3rd →	
FILTER/CONTROL PERIOD								
PHLEBITIS SCORE		0	0 1+	1+	1+	1+	0	1+
TEMPERATURE	°C	37,8	37	36,3	35,5	36	35,9	36,2
PULSE RATE	.m	62	60	68	72	80	64	90
RESPIRATORY RATE	.m	20	20	20	18	18	20	24
BLOOD PRESSURE	mm Hg	110/70	120/80	130/90	110/70	115/75	120/90	110/70
E S R	mm.h	75	87	-	72	116	95	47
W B C COUNT	x10⁹.ℓ	10,2	9	-	7,4	7	6,5	8,6
HAEMATOCRIT		,342	,364	-	,368	,368	,400	,384
HAEMOGLOBIN	g.dℓ	11,7	12	-	12,2	12,5	12,6	12,7

MEDICINES
- Penicillin 2mu IV .6h
- Chloramphenicol 1g IV .6h
- Streptomycin 1g IM .d
- Isoniazid 400 mg po .d
- Pyrazinamide 1,2g po .d
- Rifampicin 450mg po .d
- Pyridoxine 25mg po .d

INTRAVENOUS FLUIDS: NS | M

Microbiology

1st Cannulation site
Filter NG
Cannula NG
Swabs NG

2nd Cannulation site
Cannula) Discarded by
Swabs) ward staff

3rd Cannulation site
Filter 1 Bacillus species
Filter 2 NG
Cannula Staphylococcus epidermidis
Swabs Staphylococcus epidermidis

	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION	1,3d*	3,7d*	1,8d°
OUTCOME Final phlebitis score	0	1+	1+
Days to phlebitis	N/A	N/A	N/A

* Discontinued due to blockage of access line
° Elective removal of IV line

PATIENT 047 Black Male Age 35 years Mass 46kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae
Chronic alcoholism with peripheral neuropathy, proximal myopathy and cirrhosis
Delirium tremens
Pellagra

ALCOHOL INTAKE [5]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →			
FILTER/CONTROL PERIOD							
PHLEBITIS SCORE		0	1+	3+	0	0	0
TEMPERATURE	°C	38,2	36,3	37,3	37,5	36,2	37,7
PULSE RATE	.m	152	92	120	96	100	120
RESPIRATORY RATE	.m	40	32	40	40	42	40
BLOOD PRESSURE	mm Hg	130/80	130/90	150/90	120/75	120/70	110/70
E S R	mm.h	60	70	68	95	104	123
W B C COUNT	x10⁹.ℓ	9,2	11,6	17,7	23,4	22	14,3
HAEMATOCRIT		,248	,271	,284	,262	,250	,247
HAEMOGLOBIN	g.dℓ	8,1	9	9,1	8,5	7,7	7,8

MEDICINES
- Cefamandole 1,5g IV .8h
- Tobramycin 80mg IV .8h
- Penicillin 2mu IV .6h
- Vitamin B Co 2ml IV .12h
- Potassium chloride 3g IV .12h
- Indomethacin 25mg po tds
- 'Kloref' 2po qid

INTRAVENOUS FLUIDS: M

Microbiology

1st Cannulation site
Filter 1 Bacillus species
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

2nd Cannulation site
Cannula) Discarded by
Swabs) ward staff

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,5d	2,9d*
OUTCOME Final phlebitis score	3+	0
Days to phlebitis	2,5	N/A

* Discontinued due to infiltration into tissues

PATIENT 048 Black Male Age 17 years Mass 60kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →			
FILTER/CONTROL PERIOD		▨	▨	▨	▒	▒	▒
PHLEBITIS SCORE		1+	0	1+	2+	3+	4+
TEMPERATURE	°C	36,7	37	36,2	36,4	36,2	36
PULSE RATE	.m	64	80	60	72	60	72
RESPIRATORY RATE	.m	24	20	24	20	24	20
BLOOD PRESSURE	mm Hg	110/70	110/70	120/70	100/80	115/70	130/80
E S R	mm.h	93	90	92	72	58	75
W B C COUNT	$x10^9.\ell$	8,8	9,9	7,2	6,5	6,6	7,4
HAEMATOCRIT		,410	,400	,386	,397	,417	,438
HAEMOGLOBIN	g.dℓ	13,3	13,2	13,1	12,9	13,7	14,7

MEDICINES Ceftazidime 1g IV .8h

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

2nd Cannulation site

Cannula NG
Swab 1 i Micrococcus species
ii Staphylococcus epidermidis
Swab 2 NG

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	2,5d*	3,2d
OUTCOME Final phlebitis score	1+	4+
Days to phlebitis	N/A	1

* Elective removal of IV line

PATIENT 049 Black Male Age 58 years

DIAGNOSIS Bronchopneumonia
Bronchiectasis
Chronic obstructive airways disease

ALCOHOL INTAKE [4]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →						
FILTER/CONTROL PERIOD		▒	▒	▒	▒	▒	▒	▒
PHLEBITIS SCORE		0	0	0	0	0	2+	2+
TEMPERATURE	°C	36,7	37	36,4	36,3	36	36,3	36,4
PULSE RATE	.m	72	64	74	78	70	76	64
RESPIRATORY RATE	.m	24	24	20	24	28	24	28
BLOOD PRESSURE	mm Hg	130/90	160/100	180/100	130/90	150/100	140/90	140/90
E S R	mm.h	110	93	98	-	85	92	100
W B C COUNT	$x10^9.\ell$	6,4	7	7,4	-	6,6	6,6	7,1
HAEMATOCRIT		,300	,313	,334	-	,319	,303	,341
HAEMOGLOBIN	g.dℓ	9,7	9,9	10,4	-	10	10	10,9

MEDICINES Penicillin 2 - 2,5mu IV .6h

Microbiology

Cannula NG
Swabs NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION	6,7d
OUTCOME Final phlebitis score	2+
Days to phlebitis	5,6

PATIENT 050 Black Male Age 47 years

DIAGNOSIS Perforated gastric ulcer
Carcinoma of stomach
Gastrectomy

ALCOHOL INTAKE [3]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		←1st→				
FILTER/CONTROL PERIOD						
PHLEBITIS SCORE		1+	1+	1+	2+	3+
TEMPERATURE	°C	37,7	38,4	37,3	36,8	36
PULSE RATE	.m	88	94	84	80	80
RESPIRATORY RATE	.m	20	20	24	20	24
BLOOD PRESSURE	mm Hg	170/80	130/80	120/70	130/70	120/80
E S R	mm.h	11	35	90	102	98
W B C COUNT	$x10^9$.ℓ	14,5	20,1	15,4	10,7	9,4
HAEMATOCRIT		,466	,483	,410	,372	,376
HAEMOGLOBIN	g.dℓ	15,4	16	13,7	11,8	12,5

Microbiology

Cannula 1 Staphylococcus epidermidis
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES
Rolitetracycline 275mg IV.12h
Tetracycline 500mg po .6h
Papaveretum 15mgIM.6h
Dextropropoxyphene 130mg po .6h prn

INTRAVENOUS FLUIDS PB M

TOTAL DURATION OF INFUSION 4,8d

OUTCOME
Final phlebitis score 3+
Days to phlebitis 3,8

PATIENT 051 Coloured Male Age 20 years Mass 47kg

DIAGNOSIS Pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		←1st→		←2nd→		
FILTER/CONTROL PERIOD						
PHLEBITIS SCORE		0	2+	1+	1+	0
TEMPERATURE	°C	36,2	35,8	36,5	36	36
PULSE RATE	.m	92	72	80	64	58
RESPIRATORY RATE	.m	30	20	30	24	18
BLOOD PRESSURE	mm Hg	130/90	130/70	130/70	140/80	120/80
E S R	mm.h	-	24	16	16	14
W B C COUNT	$x10^9$.ℓ	-	8,8	9,4	6,9	8
HAEMATOCRIT		-	,360	,403	,393	,397
HAEMOGLOBIN	g.dℓ	-	11,7	13,6	13	13,5

Microbiology

1st Cannulation site
Cannula NG
Swab 1 Micrococcus species
Swab 2 NG

2nd Cannulation site
Filter 1 Bacillus species
Filter 2 NG
Filter 3 NG
Cannula NG
Swab 1 Bacillus species
Swab 2 NG

MEDICINES
Cefamandole 1,5g IV .8h
Indomethacin 25mg po tds
Paracetamol 1g po tds prn

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION		1st Cannulation site 1,7d	2nd Cannulation site 3d*
OUTCOME	Final phlebitis score	2+	0
	Days to phlebitis	1,7	N/A

* Elective removal of IV line

PATIENT 052 Black Male Age 46 years Mass 46kg

DIAGNOSIS Lung abscess
Carcinoma of oesophagus

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		←		1st		→
FILTER/CONTROL PERIOD						
PHLEBITIS SCORE		0	2+	3+	3+	3+
TEMPERATURE	°C	37	37,2	36,3	36,2	36,6
PULSE RATE	.m	100	88	80	72	80
RESPIRATORY RATE	.m	30	28	24	24	28
BLOOD PRESSURE	mm Hg	120/80	110/70	120/80	130/70	110/70
E S R	mm.h	-	-	-	-	-
W B C COUNT	$x10^9.\ell$	10,6	-	-	-	-
HAEMATOCRIT		,312	-	-	-	-
HAEMOGLOBIN	g.dℓ	12,2	-	-	-	-

Microbiology
Cannula NG
Swabs NG

MEDICINES Penicillin 2,5mu IV .6h →
Metronidazole 400mg po tds

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 4,6d

OUTCOME Final phlebitis score 3+
Days to phlebitis 1,7

PATIENT 053 Black Male Age 53 years Mass 49kg

DIAGNOSIS Bronchopneumonia
Chronic obstructive airways disease with bilateral lung fibrosis
Cardiomyopathy
Allergy to penicillin

ALCOHOL INTAKE [3]
SMOKING [2]

DAY OF STUDY		1	2
CANNULATION SITE		← 1st →	
FILTER/CONTROL PERIOD			
PHLEBITIS SCORE		2+	3+
TEMPERATURE	°C	36	35,6
PULSE RATE	.m	80	92
RESPIRATORY RATE	.m	30	32
BLOOD PRESSURE	mm Hg	110/70	120/90
E S R	mm.h	83	49
W B C COUNT	$x10^9.\ell$	7,3	5,6
HAEMATOCRIT		,395	,356
HAEMOGLOBIN	g.dℓ	13,1	11,9

Microbiology
Filter NG
Cannula Bacillus species
Swabs Bacillus species

MEDICINES ↑Penicillin 2mu IV
↑Hydrocortisone 200mg IV
Erythromycin 250mg po qid →

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 1,5d

OUTCOME Final phlebitis score 3+
Days to phlebitis 0,5

PATIENT 054 Coloured Male Age 61 years Mass 46kg

DIAGNOSIS Lung abscess
Pneumonia - bacteriological diagnosis not established
Previous pulmonary tuberculosis

ALCOHOL INTAKE [2]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →					← 2nd →	
FILTER/CONTROL PERIOD		▨	▨	▨	▨	▨	▨	
PHLEBITIS SCORE		0	1+	1+	1+	1+	2+	2+
TEMPERATURE	°C	35,7	36,3	35,7	36,3	36,3	36,2	36,2
PULSE RATE	.m	72	88	72	80	80	80	80
RESPIRATORY RATE	.m	20	30	24	24	20	28	24
BLOOD PRESSURE	mm Hg	120/80	130/90	120/80	120/90	120/80	110/50	-
E S R	mm.h	48	50	-	38	45	33	-
W B C COUNT	$x10^9$.ℓ	6,2	5,3	-	5,1	5,8	5,2	-
HAEMATOCRIT		,337	,348	-	,490	,344	,360	-
HAEMOGLOBIN	g.dℓ	10,5	11,4	-	11,5	11,1	11,8	-

MEDICINES
14d +Penicillin 2,5mu IV .6h
8d +Metronidazole 400mg po tds
'Moduretic' 1 po .d

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Cannula NG
Swabs NG

2nd Cannulation site

Cannula NG
Swabs NG

INTRAVENOUS FLUIDS NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	5d*	1,2d
OUTCOME Final phlebitis score	1+	2+
Days to phlebitis	N/A	1

* Elective removal of IV line

PATIENT 055 Black Male Age 43 years Mass 60kg

DIAGNOSIS Systemic lupus erythematosus (active)

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →						
FILTER/CONTROL PERIOD		▨	▨	▨	▨	▨	▨	▨
PHLEBITIS SCORE		1+	0	0	0	0	0	0
TEMPERATURE	°C	36,2	35,5	35,5	35,9	36,4	35,8	35,6
PULSE RATE	.m	80	74	72	72	80	88	80
RESPIRATORY RATE	.m	32	32	30	32	30	28	28
BLOOD PRESSURE	mm Hg	130/80	110/70	100/70	140/80	120/80	125/80	120/80
E S R	mm.h	-	-	-	-	-	-	-
W B C COUNT	$x10^9$.ℓ	-	-	-	-	-	-	-
HAEMATOCRIT		-	-	-	-	-	-	-
HAEMOGLOBIN	g.dℓ	-	-	-	-	-	-	-

MEDICINES
↑ Methyl prednisolone 1g IV
Indomethacin 50mg po tds →

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION	7d*
OUTCOME Final phlebitis score	1+
Days to phlebitis	N/A

* Discontinued due to infiltration into tissues

PATIENT 056 Coloured Male Age 18 years Mass 55kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae

ALCOHOL INTAKE [1]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →				
FILTER/CONTROL PERIOD		//////	//////	//////	//////	//////
PHLEBITIS SCORE		0	0	0	0	0
TEMPERATURE	°C	35,8	35,4	36,1	35,9	36,4
PULSE RATE	.m	68	58	72	64	62
RESPIRATORY RATE	.m	24	20	20	28	24
BLOOD PRESSURE	mm Hg	110/70	110/70	120/60	120/70	120/70
E S R	mm.h	95	69	55	46	30
W B C COUNT	$x10^9$.ℓ	4,7	4,7	6,8	6,9	5,9
HAEMATOCRIT		,362	,344	,396	,413	,418
HAEMOGLOBIN	g.dℓ	12,4	11,9	13,7	14,1	14

MEDICINES 1d +Ceftazidime 1g IV .8h

Microbiology

Filter 1 i Staphylococcus epidermidis
ii Nonhaemolytic streptococci
Filter 2 i Staphylococcus epidermidis
ii Nonhaemolytic streptococci
Filter 3 NG
Filter 4 NG
Filter 5 NG
Cannula NG
Swab 1 Staphylococcus epidermididis
Swab 2 NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 5d*

OUTCOME Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line

PATIENT 057 Black Male Age 34 years Mass 49kg

DIAGNOSIS Pneumonia - Klebsiella pneumoniae
Lung abscess
Chronic obstructive airways disease

ALCOHOL INTAKE [4]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		← 1st →						
FILTER/CONTROL PERIOD		//////	//////	//////	//////	//////	//////	
PHLEBITIS SCORE		0	0	0	1+	2+	2+	2+
TEMPERATURE	°C	35,8	36	36,2	36,2	36	36	36,6
PULSE RATE	.m	78	72	80	80	76	72	68
RESPIRATORY RATE	.m	28	30	28	24	24	24	24
BLOOD PRESSURE	mm Hg	110/70	110/70	100/70	100/60	100/60	120/80	-
E S R	mm.h	87	92	105	76	86	103	90
W B C COUNT	$x10^9$.ℓ	7,9	9	-	6,8	6,2	9,3	7,3
HAEMATOCRIT		,328	,357	-	,332	,359	-	,371
HAEMOGLOBIN	g.dℓ	10,8	11,8	-	10,4	11,6	11,5	11,7

MEDICINES 11d +Penicillin 2,5mu IV .6h
11d +Metronidazole 400mg po tds
10d +Paracetamol 1g po qid

Microbiology

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Filter 7 NG
Cannula NG
Swabs NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 6,1d

OUTCOME Final phlebitis score 2+
Days to phlebitis 5

PATIENT 058 Coloured Male Age 33 years Mass 62kg

DIAGNOSIS Mitral stenosis
Rheumatic heart disease, chronic
Atrial fibrillation
Chronic alconolism

ALCOHOL INTAKE [5]
SMOKING [4]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD					
PHLEBITIS SCORE		1+	2+	3+	3+
TEMPERATURE	°C	35,6	36,1	36,3	-
PULSE RATE	.m	80	84	72	-
RESPIRATORY RATE	.m	20	24	20	-
BLOOD PRESSURE	mm Hg	100/70	115/70	110/70	-
E S R	mm.h	8	6	8	-
W B C COUNT	x10⁹.ℓ	3	3,6	3,6	-
HAEMATOCRIT		,462	,472	-	-
HAEMOGLOBIN	g.dℓ	15,9	16,3	15,9	-

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES
Clothiapine 60mg IV
Diazepam 10mg IV
Digoxin 0,25mg po .d →
'Moduretic' 2 po .d →

INTRAVENOUS FLUIDS D5 | NS

TOTAL DURATION OF INFUSION 3,1d

OUTCOME
Final phlebitis score 3+
Days to phlebitis 2

PATIENT 059 Black Female Age 19 years Mass 60kg

DIAGNOSIS Pyelonephritis - Klebsiella species

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8
CANNULATION SITE		← 1st →		← 2nd →					
FILTER/CONTROL PERIOD									
PHLEBITIS SCORE		1+	2+	0	1+	1+	1+	1+	3+
TEMPERATURE	°C	35,4	35,4	36	36	35,7	35,3	35,1	35,8
PULSE RATE	.m	100	92	84	92	84	84	68	84
RESPIRATORY RATE	.m	24	26	24	24	20	20	18	24
BLOOD PRESSURE	mm Hg	100/60	90/60	110/70	100/50	90/60	100/50	120/70	110/60
E S R	mm.h	114	113	136	115	83	109	99	>150
W B C COUNT	x10⁹.ℓ	7,8	9,4	10	8,4	9,4	7,4	7,2	8,1
HAEMATOCRIT		,263	,271	-	,249	,284	,267	,290	,295
HAEMOGLOBIN	g.dℓ	8,7	9,2	8,7	8	9,4	8,6	8,9	9,7

Microbiology

1st Cannulation site
Cannula NG
Swab 1 i Staphylococcus epidermidis
ii Nonhaemolytic streptococci
iii Bacillus species
Swab 2 NG

2nd Cannulation site
Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Cannula NG
Swabs NG

MEDICINES
Cefamandole 2g IV .6h →
Metronidazole 400mg po tds →
Nalidixic acid 1g po qid →
Slow K' 2 po qid →

INTRAVENOUS FLUIDS NS | D5

TOTAL DURATION OF INFUSION 1st Cannulation site 1,9d; 2nd Cannulation site 6d

OUTCOME
Final phlebitis score 1st Cannulation site 2+; 2nd Cannulation site 3+
Days to phlebitis 1st Cannulation site 1,9; 2nd Cannulation site 6

PATIENT 060 Black Male Age 64 years Mass 60kg

DIAGNOSIS Cardiomyopathy, restrictive
Congestive cardiac failure

ALCOHOL INTAKE [6]
SMOKING [6]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD		▒▒▒▒▒▒▒▒▒▒		
PHLEBITIS SCORE		0	1+	1+
TEMPERATURE	°C	35,5	36,3	36,2
PULSE RATE	.m	76	76	80
RESPIRATORY RATE	.m	24	20	28
BLOOD PRESSURE	mm Hg	110/70	115/65	110/60
E S R	mm.h	5	-	7
W B C COUNT	$x10^9$.ℓ	5,5	-	5,2
HAEMATOCRIT		,416	-	-
HAEMOGLOBIN	g.dℓ	13,2	-	13,4

MEDICINES
3d +Furosemide 80mg po bd
3d +Prazosin 10mg po bd
3d +Isosorbide dinitrate 10mg po qid
3d +'Slow K' 3 po bd

INTRAVENOUS FLUIDS [NS]

TOTAL DURATION OF INFUSION 2,8d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Elective removal of IV line

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

PATIENT 061 Coloured Male Age 31 years

DIAGNOSIS Chronic duodenal ulcer
Acute antral erosions
Vagotomy and antrectomy

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st	→ ← 2nd →	
FILTER/CONTROL PERIOD		▨▨▨▨	▒▒▒▒	
PHLEBITIS SCORE		0	1+ 1+	3+
TEMPERATURE	°C	37,2	37	37
PULSE RATE	.m	96	96	88
RESPIRATORY RATE	.m	20	24	28
BLOOD PRESSURE	mm Hg	130/90	140/80	130/90
E S R	mm.h	77	100	77
W B C COUNT	$x10^9$.ℓ	10,2	7,9	7,9
HAEMATOCRIT		-	,408	,402
HAEMOGLOBIN	g.dℓ	13,3	13,5	13

MEDICINES 2d +Cefamandole 1g IV.6h

INTRAVENOUS FLUIDS [M] [RF] [M] [RF] [M]

Microbiology

1st Cannulation site

Filter 1 Discarded
Filter 2 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 i Staphylococcus epidermidis
ii Enterococcus species

2nd Cannulation site

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	1,2d*	1,8d
OUTCOME Final phlebitis score	1+	3+
Days to phlebitis	N/A	1,7

* Discontinued due to blockage of access line and local pain

PATIENT 081 Coloured male Age 50 years

DIAGNOSIS Superficial burns
Cellulitis - β haemolytic streptococci and Staphylococcus aureus
Skin graft

ALCOHOL INTAKE [5]
SMOKING [6]

DAY OF STUDY		1	2
CANNULATION SITE		⟵ 1st ⟶	
FILTER/CONTROL PERIOD			
PHLEBITIS SCORE		0	2+
TEMPERATURE	°C	37,5	37
PULSE RATE	.m	80	92
RESPIRATORY RATE	.m	24	24
BLOOD PRESSURE	mm Hg	150/90	140/90
E S R	mm.h	30	-
W B C COUNT	$x10^9.\ell$	9,4	13,8
HAEMATOCRIT		,430	,460
HAEMOGLOBIN	g.dℓ	14,5	15,4

Microbiology

Cannula) Discarded by
Swabs) ward staff

MEDICINES Erythromycin 300mg IV .6h
Dextropropoxyphene 130mg po .6h

INTRAVENOUS FLUIDS [NS] [M]

TOTAL DURATION OF INFUSION 1,4d

OUTCOME Final phlebitis score 2+
Days to phlebitis 1,2

APPENDIX III

Summary account of incompleted studies not included in the final statistical analysis

Code

Patient numbers beginning with zero refer to patients who also have cannulation sites included in the final statistical analysis; patient numbers beginning with one refer to patients with only incompleted studies.

Group

F = Filter included in-line

C = Control - no filter in-line

Sex

M = Male

F = Female

Reason for exclusion from statistical analysis

1 Blood administered

2 Elective removal of access line prior to 30 hours

3 Blockage of access line prior to 30 hours

4 Infiltration of infusion fluid into tissues prior to 30 hours

5 Patient non-compliance

6 Patient not examined after infusion discontinued

7 Patient deceased

PATIENT 062 Coloured Male Age 58 years

DIAGNOSIS Cholecystitis due to cholelithiasis
Cholecystectomy

ALCOHOL INTAKE [1]
SMOKING [2]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD				
PHLEBITIS SCORE		1+	1+	3+
TEMPERATURE	°C	37	37,2	36
PULSE RATE	.m	84	100	60
RESPIRATORY RATE	.m	30	38	24
BLOOD PRESSURE	mm Hg	130/90	130/90	140/80
E S R	mm.h	17	-	50
W B C COUNT	$x10^9$.ℓ	8,5	-	4,9
HAEMATOCRIT		,416	-	,456
HAEMOGLOBIN	g.dℓ	14,3	-	14,8

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES

Rolitetracycline 275mg IV .12h
Papaverecum 15mg IM .6h

INTRAVENOUS FLUIDS PB M

TOTAL DURATION OF INFUSION 3d

OUTCOME Final phlebitis score 3+
Days to phlebitis 2,1

PATIENT 063 Black Male Age 29 years Mass 52kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established
Pulmonary tuberculosis
Syphilis

ALCOHOL INTAKE [1]
SMOKING [2]

DAY OF STUDY		1	2
CANNULATION SITE		← 1st →	
FILTER/CONTROL PERIOD			
PHLEBITIS SCORE		1+	1+
TEMPERATURE	°C	37,5	36,4
PULSE RATE	.m	88	88
RESPIRATORY RATE	.m	30	28
BLOOD PRESSURE	mm Hg	130/70	120/60
E S R	mm.h	104	110
W B C COUNT	$x10^9$.ℓ	11,6	10,7
HAEMATOCRIT		,405	,388
HAEMOGLOBIN	g.dℓ	13,5	12,6

Microbiology

Cannula NG
Swabs NG

MEDICINES

Cefamandole 2g IV
Penicillin 4mu IV
Amoxycillin 250mg po tds →
Aminophylline 250mg IV
Furosemide 40mg IV

INTRAVENOUS FLUIDS M

TOTAL DURATION OF INFUSION 1,6d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Elective removal of IV line

PATIENT 064 Black Male Age 40 years Mass 69kg

DIAGNOSIS Acute glomerulonephritis with nephrosis
Deep vein thrombosis
Hypertension
Chronic lung disease

Microbiology

Cannula) Discarded by
Swabs) ward staff

ALCOHOL INTAKE [2]

SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CANNULATION SITE		← 1st →															
FILTER/CONTROL PERIOD																	
PHLEBITIS SCORE		0	1+	1+	1+	2+	2+	1+	2+	2+	1+	1+	1+	1+	1+	1+	1+
TEMPERATURE	°C	37,2	37	37,2	36,5	36	36,1	36,7	36,4	36	36	36,6	36,4	36,4	36,2	36,9	36,8
PULSE RATE	.m	120	92	100	92	110	102	100	92	120	100	110	96	104	96	98	98
RESPIRATORY RATE	.m	40	30	20	24	28	24	20	24	30	24	28	24	24	20	24	24
BLOOD PRESSURE	mm Hg	160/110	170/100	170/110	160/100	160/100	175/110	180/120	160/100	180/120	180/120	180/120	180/130	170/120	160/90	120/80	130/80
E S R	mm.h	60	> 150	> 150	136	150	-	> 150	144	145	> 150	150	> 150	-	-	-	-
W B C COUNT	$x10^9.\ell$	18,6	14,7	14,6	17,4	19,5	21,5	20,8	18,2	15,7	16	17	13,4	16,4	-	-	-
HAEMATOCRIT		,316	,299	,293	,300	,256	,280	,286	,287	,230	,264	,240	,244	,264	-	-	-
HAEMOGLOBIN	g.dℓ	9,6	9,5	9,4	9,7	8,4	8,8	9,1	9,4	8,3	8,6	8	7,5	8,3	-	-	-

MEDICINES

Heparin 6-12000u IV .6h
Penicillin 2mu IV .6h
Cefamandole 1g IV .6h
Prazosin 2-10mg po bd
Atenolol 50mg po .d
Warfarin 5mg po .d
'Slow K' 1 po tds

INTRAVENOUS FLUIDS

Potassium chloride 1,5g IV — NS

TOTAL DURATION OF INFUSION 15,6d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Elective removal of IV line

PATIENT 065 Coloured Male Age 49 years Mass 47kg

DIAGNOSIS Pleural effusion
Chronic alcoholism
Chronic obstructive airways disease
Chronic pancreatitis

ALCOHOL INTAKE [5]
SMOKING [6]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →		← 3rd →	
FILTER/CONTROL PERIOD		▨		▨		▨	
PHLEBITIS SCORE		0	2+	0	2+	2+	3+
TEMPERATURE	°C	36,9	36,6	36,7	36,9	36,7	36,4
PULSE RATE	.m	80	70	74	84	78	80
RESPIRATORY RATE	.m	24	24	24	20	24	20
BLOOD PRESSURE	mm Hg	120/80	120/70	120/80	120/80	100/60	110/70
E S R	mm.h	125	> 150	-	138	-	105
W B C COUNT	$x10^9.\ell$	12,1	10,6	9,6	10,3	-	8,3
HAEMATOCRIT		,366	,388	,360	,361	-	,361
HAEMOGLOBIN	g.dℓ	12	12,9	12	11,8	-	11,4
MEDICINES	2d	+Cefamandole 1g IV .6h					
	2d	+Penicillin 3mu IV .6h					

Microbiology

1st Cannulation site
Filter 1 NG
Filter 2 NG
Cannula NG
Swabs NG

2nd Cannulation site
Filter 1 NG
Filter 2 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

3rd Cannulation site
Cannula NG
Swab 1 i Staphylococcus epidermidis
ii Bacillus rotans
Swab 2 NG

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION		1st Cannulation site 1,8d	2nd Cannulation site 1,9d	3rd Cannulation site 2d
OUTCOME	Final phlebitis score	2+	2+	3+
	Days to phlebitis	1,8	1,9	0,9

PATIENT 066 Black Male Age 25 years Mass 65kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [5]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5
CANNULATION SITE		← 1st →				
FILTER/CONTROL PERIOD		▨				
PHLEBITIS SCORE		0	0	0	0	0
TEMPERATURE	°C	36,4	36,5	35,6	36,2	36,1
PULSE RATE	.m	72	80	72	76	76
RESPIRATORY RATE	.m	28	24	24	20	24
BLOOD PRESSURE	mm Hg	105/60	110/70	100/70	110/70	130/70
E S R	mm.h	116	121	135	91	125
W B C COUNT	$x10^9.\ell$	18,4	13,7	9,2	11,5	9,9
HAEMATOCRIT		-	,400	,418	,377	,419
HAEMOGLOBIN	g.dℓ	13,5	13	13,4	12,6	13,3
MEDICINES		Ceftazidime 1g IV .8h				
		Paracetamol 1g po tds prn				

Microbiology

Cannula NG
Swab 1 Bacillus rotans
Swab 2 Staphylococcus epidermidis

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION		4,6d*
OUTCOME	Final phlebitis score	0
	Days to phlebitis	N/A

* Elective removal of IV line

PATIENT 067 Coloured Female Age 22 years Mass 45kg

DIAGNOSIS Pleural effusion
Pulmonary tuberculosis

Microbiology

1st Cannulation site

Filter 1	NG
Filter 2	NG
Cannula	NG
Swabs	NG

2nd Cannulation site

Filter 1	NG
Filter 2	NG
Filter 3	Staphylococcus epidermidis
Filter 4	Staphylococcus epidermidis
Cannula	NG
Swabs	NG

3rd Cannulation site

Cannula		NG
Swab	1	Staphylococcus epidermidis
Swab	2	NG

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8	9	10	11
CANNULATION SITE		← 1st →	← 2nd →				← 3rd →					
FILTER/CONTROL PERIOD												
PHLEBITIS SCORE		0	2+ 0	0	2+	3+	0	0	0	0	0	0
TEMPERATURE	°C	37	36,4	36,4	36,8	36,6	36,8	36,9	36	36,2	36,6	36,2
PULSE RATE	.m	94	100	88	100	92	80	84	90	80	88	84
RESPIRATORY RATE	.m	28	24	20	24	28	20	24	20	20	22	24
BLOOD PRESSURE	mm Hg	110/70	110/70	130/90	130/80	120/70	120/70	120/70	130/70	120/80	120/70	110/60
E S R	mm.h	110	140	111	112	135	> 150	-	102	115	90	102
W B C COUNT	x10⁹.ℓ	6,6	6	5,4	6,3	6,7	5,9	6,4	6,4	5,4	5,8	5,8
HAEMATOCRIT		,405	,372	,377	,366	,357	,313	,299	,383	,429	,407	,375
HAEMOGLOBIN	g.dℓ	13,3	12,1	12,2	12,4	12	10,8	9,2	12,6	13,6	13,2	12,9

MEDICINES
Penicillin 2mu IV .6h
Paracetamol 1g po .6h prn

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
TOTAL DURATION OF INFUSION	1,3d	3,7d	6d*
OUTCOME — Final phlebitis score	2+	3+	0
OUTCOME — Days to phlebitis	1,2	2,5	N/A

* Elective removal of IV line

PATIENT 068 Black Female Age 47 years

DIAGNOSIS Pyelonephritis
Renal failure, chronic end stage
Hypertension

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →					← 2nd →			
FILTER/CONTROL PERIOD										
PHLEBITIS SCORE		0	0	1+	1+	1+	2+	0	1+	3+
TEMPERATURE	°C	38	36,6	36,4	36,9	37,3	37	37	36,5	36,2
PULSE RATE	.m	64	68	60	72	64	60	84	64	60
RESPIRATORY RATE	.m	24	20	20	20	24	20	24	28	20
BLOOD PRESSURE	mm Hg	140/100	150/100	160/90	150/100	150/80	160/90	190/120	150/90	130/70
E S R	mm.h	> 150	> 150	> 150	-	> 150	130	-	> 150	> 150
W B C COUNT	x10⁹.ℓ	15	11	9,3	-	7	6,7	-	6,2	7,7
HAEMATOCRIT		,278	,297	,286	-	,228	,289	-	,292	,282
HAEMOGLOBIN	g.dℓ	8,9	9,4	9,2	-	6,5	9	-	8,8	8,8

Microbiology

1st Cannulation site

Filter 1	NG
Filter 2	NG
Filter 3	Staphylococcus epidermidis
Filter 4	NG
Filter 5	NG
Filter 6	NG
Cannula	NG
Swab 1	Bacillus species
Swab 2	Micrococcus species

2nd Cannulation site

Cannula		NG
Swab	1	Staphylococcus epidermidis
Swab	2	NG

MEDICINES
Cefamandole 500mg IV .8h
Potassium chloride 1,5g IV .d
Metronidazole 400mg po tds
3d +Furosemide 40mg po .d
14d +Prazosin 4mg po bd
11d +Atenolol 100mg po .d
Dextropropoxyphene 130mg po .6h

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	5,2d	3,3d
OUTCOME — Final phlebitis score	2+	3+
OUTCOME — Days to phlebitis	5,2	3,3

PATIENT 069 Black Female Age 25 years

DIAGNOSIS Pelvic inflammatory disease - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD		//////	//////	
PHLEBITIS SCORE		0	0	0
TEMPERATURE	°C	37	37,4	-
PULSE RATE	.m	94	120	-
RESPIRATORY RATE	.m	24	28	-
BLOOD PRESSURE	mm Hg	130/70	110/90	-
E S R	mm.h	60	85	-
W B C COUNT	$x10^9.\ell$	22,1	23,2	-
HAEMATOCRIT		,394	,418	-
HAEMOGLOBIN	g.dℓ	13,9	14,3	-

Microbiology

Filter 1 Staphylococcus epidermidis
Filter 2 NG
Filter 3 NG
Cannula NG
Swabs NG

MEDICINES
Ampicillin 500mg IV .6h
Papaveretum 10mg IM .4h
Metronidazole 400mg po .8h
Mefenamic acid 500mg po tds →

INTRAVENOUS FLUIDS [D5 | NS | M]

TOTAL DURATION OF INFUSION 2,2d*

OUTCOME Final phlebitis score 0
Days to phlebitis N/A

* Discontinued due to blockage of access line

PATIENT 070 Black Male Age 24 years Mass 46kg

DIAGNOSIS Pneumonia - possibly due to Enterobacter cloacae
Renal failure, acute
Myositis

ALCOHOL INTAKE [1]
SMOKING [3]

DAY OF STUDY		1	2
CANNULATION SITE		← 1st →	
FILTER/CONTROL PERIOD		.....	
PHLEBITIS SCORE		-	3+
TEMPERATURE	°C	36,6	36
PULSE RATE	.m	92	76
RESPIRATORY RATE	.m	28	30
BLOOD PRESSURE	mm Hg	140/110	150/110
E S R	mm.h	87	77
W B C COUNT	$x10^9.\ell$	10,9	13,5
HAEMATOCRIT		,395	,337
HAEMOGLOBIN	g.dℓ	13,8	10,6

Microbiology

Cannula) Discarded by
Swabs) patient

MEDICINES
Cefamandole 1g IV .8h →
Paracetamol 1g po .6h →

INTRAVENOUS FLUIDS [NS]

TOTAL DURATION OF INFUSION 1,6d

OUTCOME Final phlebitis score 3+
Days to phlebitis 1,2

PATIENT 071 Coloured Male Age 49 years Mass 57kg

DIAGNOSIS Pneumonia - Klebsiella pneumoniae

ALCOHOL INTAKE [4]
SMOKING [4]

DAY OF STUDY		1	2	3	4	5	6	7	8	9
CANNULATION SITE		← 1st →			← 2nd →					
FILTER/CONTROL PERIOD		▨			▨					
PHLEBITIS SCORE		0	0	0	2+	0	1+	2+	3+	3+
TEMPERATURE	°C	37,3	37,5	36,5	36,4	37,1	37	37	36,5	36,9
PULSE RATE	.m	92	88	72	88	88	88	84	92	84
RESPIRATORY RATE	.m	28	32	24	30	20	32	24	28	24
BLOOD PRESSURE	mm Hg	120/70	130/80	120/80	120/80	120/80	150/100	150/100	140/90	120/70
E S R	mm.h	100	120	103	75	106	137	132	> 150	140
W B C COUNT	x10⁹.ℓ	11,3	9,3	10	8	6,9	6,1	7,9	8,4	8,4
HAEMATOCRIT		,329	,330	,267	,343	,296	,309	,322	,337	,309
HAEMOGLOBIN	g.dℓ	10,9	10,9	8,7	11	9,9	10,1	10,7	11,1	10,3

Microbiology

1st Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 Discarded
Filter 4 NG
Cannula NG
Swabs NG

2nd Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3 NG
Filter 4 NG
Filter 5 NG
Filter 6 NG
Cannula i Staphylococcus epidermidis
ii Enterococcus species
Swabs NG

MEDICINES

Cefamandole 1g IV .8h →
Tobramycin 80mg IV .8h →
Potassium chloride 1,5g IV
Paracetamol 1g po .6h prn →

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	3,1d	5,7d
OUTCOME — Final phlebitis score	2+	3+
Days to phlebitis	3,1	3,6

PATIENT 072 Coloured Male Age 17 years Mass 58kg

DIAGNOSIS Bacterial endocarditis - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →			← 2nd →		
FILTER/CONTROL PERIOD		▨			▨		
PHLEBITIS SCORE		1+	2+	0	0	1+	2+
TEMPERATURE	°C	36	35,3	36	35,7	35,3	35,8
PULSE RATE	.m	72	74	70	82	76	88
RESPIRATORY RATE	.m	30	24	20	20	24	28
BLOOD PRESSURE	mm Hg	140/10	130/0	130/30	140/0	130/30	140/40
E S R	mm.h	48	25	37	32	38	31
W B C COUNT	x10⁹.ℓ	7,6	6,7	7,6	6,8	7,1	6,8
HAEMATOCRIT		,413	,412	,375	,395	,366	,369
HAEMOGLOBIN	g.dℓ	12,9	13	11,9	12	11,9	11,9

Microbiology

1st Cannulation site

Cannula Staphylococcus epidermidis
Swab 1 i Micrococcus species
ii Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site

Filter 1 Discarded
Filter 2 NG
Filter 3 NG
Filter 4 NG
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES

Penicillin 5mu IV .6h →
2d +Furosemide 80mg po .d →
2d +Digoxin 0,25mg po .d →
2d +'Slow K' 2 po tds →

INTRAVENOUS FLUIDS: NS

	1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION	1,8d	4d
OUTCOME — Final phlebitis score	2+	2+
Days to phlebitis	1,8	4

PATIENT 073 Coloured Female Age 63 years Mass 83kg

DIAGNOSIS Septicaemia - Escherichia coli
Pleural effusion

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		←1st→	←2nd→		
FILTER/CONTROL PERIOD					
PHLEBITIS SCORE		0	2+	0	2+
TEMPERATURE	°C •	39,6	38,9	38,4	37,8
PULSE RATE	.m	126	104	110	96
RESPIRATORY RATE	.m	36	30	32	36
BLOOD PRESSURE	mm Hg	140/90	130/90	150/80	160/80
E S R	mm.h	38	-	137	> 150
W B C COUNT	$x10^9.\ell$	18	19,1	16,3	12,6
HAEMATOCRIT		-	,383	,360	,332
HAEMOGLOBIN	g.dℓ	12	12,3	11,5	10,9

Microbiology

1st Cannulation site

Cannula NG
Swabs NG

2nd Cannulation site

Filter 1 NG
Filter 2 NG
Filter 3) Discarded
Cannula) by
Swabs) ward staff

MEDICINES
Cefamandole 1g IV .8h
Dextropropoxyphene 130mg po tds prn

INTRAVENOUS FLUIDS M NS

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		1,4d	2d
OUTCOME	Final phlebitis score	2+	2+
	Days to phlebitis	1,4	1,5

PATIENT 074 Coloured Female Age 49 years Mass 97kg

DIAGNOSIS Pyelonephritis, acute, recurrent
Nephrolithiasis
Congestive cardiac failure
Angina pectoris
Hypertension

ALCOHOL INTAKE [1]
SMOKING [3]

DAY OF STUDY		1	2	3	4	5	6	7
CANNULATION SITE		←1st→			←2nd→			
FILTER/CONTROL PERIOD								
PHLEBITIS SCORE		0	0	0	0	0	0	0
TEMPERATURE	°C	37,1	37	37	37,3	36,6	36	36,9
PULSE RATE	.m	90	92	88	96	108	90	90
RESPIRATORY RATE	.m	28	30	30	32	28	30	27
BLOOD PRESSURE	mm Hg	100/60	125/80	120/70	110/70	160/90	150/90	120/80
E S R	mm.h	61	88	79	-	-	115	-
W B C COUNT	$x10^9.\ell$	19,4	13,6	-	-	-	9,4	-
HAEMATOCRIT		,393	,406	-	-	-	,426	-
HAEMOGLOBIN	g.dℓ	12,3	12,6	-	-	-	13,5	-

Microbiology

1st Cannulation site

Cannula) Discarded by
Swabs) ward staff

2nd Cannulation site

Cannula) Discarded by
Swabs) ward staff

MEDICINES
Cefamandole 1g IV .6h
Paracetamol 1g po .6h
Furosemide 40mg po .d

INTRAVENOUS FLUIDS D5 NS

		1st Cannulation site	2nd Cannulation site
TOTAL DURATION OF INFUSION		2,9d*	3,4d*
OUTCOME	Final phlebitis score	0	0
	Days to phlebitis	N/A	N/A

* Discontinued due to blockage of access line and local pain

PATIENT 075 Coloured Female Age 46 years Mass 39kg

DIAGNOSIS Bronchopneumonia - Klebsiella species
Chronic obstructive airways disease
Malnutrition
Anaemia

ALCOHOL INTAKE [4]
SMOKING [4]

DAY OF STUDY		1	2
CANNULATION SITE		← 1st →	
FILTER/CONTROL PERIOD		//////	//////
PHLEBITIS SCORE		1+	3+
TEMPERATURE	°C	36,6	36,2
PULSE RATE	.m	76	76
RESPIRATORY RATE	.m	24	20
BLOOD PRESSURE	mm Hg	110/70	110/60
E S R	mm.h	104	109
W B C COUNT	$x10^9.\ell$	7,3	6,9
HAEMATOCRIT		,310	,288
HAEMOGLOBIN	g.dℓ	9,5	9,6

Microbiology
Filter 1 NG
Filter 2 NG
Cannula NG
Swabs NG

MEDICINES
17d +Penicillin 1mu IV .6h
17d +Metronidazole 400mg po tds
5d +'Slow K' 2 po tds
17d +Salbutamol Neb .6h
17d +Thiamine 100mg po .d

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 2d

OUTCOME Final phlebitis score 3+
Days to phlebitis 2

PATIENT 076 Coloured Male Age 19 years Mass 48kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae

ALCOHOL INTAKE [6]
SMOKING [1]

DAY OF STUDY		1	2	3
CANNULATION SITE		← 1st →		
FILTER/CONTROL PERIOD		.....	.....	
PHLEBITIS SCORE		0	1+	1+
TEMPERATURE	°C	36	36	37,2
PULSE RATE	.m	110	112	110
RESPIRATORY RATE	.m	32	32	28
BLOOD PRESSURE	mm Hg	110/70	100/70	120/80
E S R	mm.h	63	84	118
W B C COUNT	$x10^9.\ell$	17,7	9,8	7
HAEMATOCRIT		,414	,380	,375
HAEMOGLOBIN	g.dℓ	13,6	13,7	12,8

Microbiology
Cannula NG
Swabs NG

MEDICINES
Penicillin 2mu IV .6h
'Codis' 2po .6h →

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 2,8d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Discontinued due to blockage of access line

PATIENT 077 Coloured Male Age 15 years Mass 32kg

DIAGNOSIS Lobar pneumonia - bacteriological diagnosis not established

ALCOHOL INTAKE [1]
SMOKING [1]

DAY OF STUDY		1	2	3	4
CANNULATION SITE		← 1st →			
FILTER/CONTROL PERIOD		[shaded]			
PHLEBITIS SCORE		0	0	0	0
TEMPERATURE	°C	36	36,4	36,1	-
PULSE RATE	.m	90	84	88	-
RESPIRATORY RATE	.m	24	24	24	-
BLOOD PRESSURE	mm Hg	110/70	110/60	110/70	-
E S R	mm.h	> 150	139	83	-
W B C COUNT	$x10^9.\ell$	10,4	6,1	6,7	-
HAEMATOCRIT		,336	,324	,360	-
HAEMOGLOBIN	g.dℓ	12,2	11,3	11,8	-

Microbiology
Cannula NG
Swabs NG

MEDICINES
Penicillin 2mu IV .6h
'Codis' 2 po .6h →

INTRAVENOUS FLUIDS
NS

TOTAL DURATION OF INFUSION 3,4d*

OUTCOME
Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line

PATIENT 078 Coloured Male Age 42 years Mass 57kg

DIAGNOSIS Lobar pneumonia - Streptococcus pneumoniae
Gout

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2	3	4	5	6
CANNULATION SITE		← 1st →		← 2nd →		← 3rd →	
FILTER/CONTROL PERIOD		[shaded]		[hatched]		[hatched]	
PHLEBITIS SCORE		0	2+	0	0	0	0
TEMPERATURE	°C	40,3	35,9	36,3	37,2	37,6	36,1
PULSE RATE	.m	98	80	76	72	64	70
RESPIRATORY RATE	.m	28	28	28	24	24	20
BLOOD PRESSURE	mm Hg	110/65	110/60	110/60	130/90	120/80	110/60
E S R	mm.h	> 150	146	112	> 150	> 150	> 150
W B C COUNT	$x10^9.\ell$	27,8	16	11,1	7,3	8,8	6,7
HAEMATOCRIT		,399	,427	,350	,366	,358	,297
HAEMOGLOBIN	g.dℓ	14,2	14,5	12,1	12,3	11,8	11

Microbiology

1st Cannulation site
Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

2nd Cannulation site
Filter 1 Staphylococcus epidermidis
Filter 2 and giving set used for 3rd cannulation site
Cannula) Discarded by ward staff

3rd Cannulation site
Filter 2 Staphylococcus epidermidis
Filter 3 Staphylococcus epidermidis
Filter 4 Staphylococcus epidermidis
Filter 5 Staphylococcus epidermidis
Cannula NG
Swabs NG

MEDICINES
Ceftazidime 1g IV .8h
Aspirin 600mg po .6h prn
Indomethacin 25mg po tds
Potassium chloride 1,5g IV
'Kloref' 1 po tds →

INTRAVENOUS FLUIDS
NS

TOTAL DURATION OF INFUSION	1st Cannulation site	2nd Cannulation site	3rd Cannulation site
	1,7d	1,8d*	1,9d*
OUTCOME Final phlebitis score	2+	0	0
Days to phlebitis	1,7	N/A	N/A

* Discontinued due to blockage of access line
* Elective removal of IV line

PATIENT 079 Coloured Male Age 25 years Mass 56kg

DIAGNOSIS Pneumonia - viral

ALCOHOL INTAKE [2]
SMOKING [2]

DAY OF STUDY		1	2
CANNULATION SITE		←1st→	
FILTER/CONTROL PERIOD			
PHLEBITIS SCORE		0	1+
TEMPERATURE	°C	37	37,6
PULSE RATE	.m	72	60
RESPIRATORY RATE	.m	24	20
BLOOD PRESSURE	mm Hg	130/80	130/80
E S R	mm.h	22	35
W B C COUNT	$x10^9.\ell$	7,8	7
HAEMATOCRIT		,410	,397
HAEMOGLOBIN	g.dℓ	13,3	13,4

Microbiology

Cannula NG
Swab 1 Staphylococcus epidermidis
Swab 2 NG

MEDICINES

Cefamandole 1,5g IV .6h
Penicillin 2mu IV .6h
Paracetamol 1g po .6h →

INTRAVENOUS FLUIDS NS

TOTAL DURATION OF INFUSION 1,9d*

OUTCOME Final phlebitis score 1+
Days to phlebitis N/A

* Discontinued due to blockage of access line and local pain

PATIENT 080 Black female Age 30 years Mass 62kg

DIAGNOSIS Bronchial asthma
Chronic bronchitis

ALCOHOL INTAKE [6]
SMOKING [1]

DAY OF STUDY		1	2
CANNULATION SITE		←1st→	
FILTER/CONTROL PERIOD			
PHLEBITIS SCORE		0	0
TEMPERATURE	°C	36,4	36
PULSE RATE	.m	120	90
RESPIRATORY RATE	.m	32	30
BLOOD PRESSURE	mm Hg	130/70	-
E S R	mm.h	88	-
W B C COUNT	$x10^9.\ell$	7,5	-
HAEMATOCRIT		,313	-
HAEMOGLOBIN	g.dℓ	10,9	-

Microbiology

Cannula) Discarded by
Swabs) ward staff

MEDICINES

Hydrocortisone 200mg IV
Aminophylline 500mg IV
Hexoprenaline 5µg IV
Amoxycillin 250mg po tds
Hexoprenaline 0,5mg subling .6h
Salbutamol Neb .4h

INTRAVENOUS FLUIDS D5

TOTAL DURATION OF INFUSION 1,5d*

OUTCOME Final phlebitis score 0
Days to phlebitis N/A

* Elective removal of IV line

Patient number	Diagnosis	Age in years	Sex	Group F/C	Duration of IV therapy h	Reason for removal from study
003	Pneumonia	57	M	C	13	4
017	"	31	M	C	10	4
				C	24	3
				C	29	3
				C	18	3
021	"	31	F	F	24	2
022	"	62	M	C	26	2
027	"	38	M	F	21	3
				F	19	3
				C	11	5
029	"	41	M	C	18	3
030	Lung abscess	30	M	F	28	3
				F	22	3
056	Pneumonia	18	M	F	20	3
057	Lung abscess	34	M	F	5	3
061	Vagotomy and antrectomy	31	M	C	22	3
				C	25	4
070	Pneumonia	24	M	F	15	5
073	Septicaemia	63	F	C	24	4
101	Total abdominal hysterectomy	44	F	C	12	1
102	"	41	F	C	24	2
103	"	42	F	F	25	2
104	"	65	F	F	24	4
				F	24	4
105	"	27	F	C	15	4
				C	15	4
106	"	47	F	C	20	4
				C	18	2
107	Pelvic inflammatory disease	31	F	C	12	2
108	Total abdominal hysterectomy	33	F	C	24	6
109	"	42	F	C	24	6
110	"	42	F	F	24	2
111	Pneumonia	41	M	F	24	2
112	"	19	M	F	24	4
				F	24	4
				F	24	4
				F	24	3
				C	18	4
113	Laparotomy, tubo-ovarian abscess	24	F	F	24	6
114	Pneumonia	29	F	C	12	2
115	"	44	M	F	4	5
116	Caesarian section and laparotomy Peritonitis	27	F	F	24	3
117	Pancreatitis	41	M	C	20	4
	Septicaemia			C	21	4
				C	17	3
				C	26	3
118	Cholecystectomy	60	F	F	23	4
				F	23	3
119	Lung abscess	23	F	C	28	3
				C	14	2
120	Diarrhoea and vomiting	72	F	F	18	3
121	Pelvic inflammatory disease	56	F	C	29	2
122	Cerebrovascular accident - arteriovenous malformation	51	F	C	24	2
123	Pneumonia	51	M	F	3	3
				F	3	3
				F	24	3
124	"	52	M	F	19	3
125	Wound sepsis - resistant Staphylococcus aureus	27	M	F	22	3
				F	9	3
126	Congestive cardiac failure Cellulitis	60	F	C	29	4
127	Bronchitis	55	M	F	14	2
128	Pneumonia	43	F	C	25	1